EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION OF AMERICA HOLDINGS,)
Plaintiff,) C.A. No. 21-669 (GBW)
V.) HIGHLY CONFIDENTIAL - ATTORNEY'S EYES ONLY
NATERA, INC.))
Defendant.)
LABORATORY CORPORATION OF AMERICA HOLDINGS,)))
Plaintiff,) C.A. No. 21-1635 (GBW)
v.)
NATERA, INC.)
Defendant.	<i>)</i>)

EXHIBIT 1: JOINT STATEMENT OF UNCONTESTED FACTS

In accordance with Local Rule 16.3(c)(3) of the Local Rules of Civil Practice and Procedure of the United States District Court for the District of Delaware, Plaintiff Laboratory Corporation of America Holdings ("Plaintiff" or "Labcorp") and Defendant Natera, Inc. ("Defendant" or "Natera") submit the following joint statement of facts that are undisputed or have been agreed or stipulated to by the parties, and for which no proof is needed at trial.

I. THE PARTIES AND NATURE OF THE CASE

A. Plaintiff

1. Plaintiff Laboratory Corporation of America Holdings is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1400 16th Street, San Francisco, California 94103.

B. Defendant

2. Defendant Natera, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 201 Industrial Road, San Carlos, California 94070.

C. Nature of the Case

- 3. This is an action for alleged patent infringement arising under the Patent Laws of the United States, Title 35, United States Code, § 1, *et seq*.
- 4. Labcorp has alleged infringement of claims 1–13 and 15–16 of U.S. Patent No. 10,604,799 (the "'799 Patent"); claims 1, 4–9, 12, and 15–27 of U.S. Patent No. 11,149,308 (the "'308 Patent"); and claims 1–13 and 15–18 of U.S. Patent No. 11,155,863 (the "'863 Patent") (collectively, with respect to the patents, the "Asserted Patents" or "Patents-in-Suit," and with respect to the claims, the "Asserted Claims") against Natera.

- 5. Natera has asserted defenses and affirmative defenses of non-infringement and invalidity of the Asserted Patents.
- 6. Subject matter jurisdiction over this action is proper pursuant to 28 U.S.C. §§ 1331 and 1338(a).
- 7. Venue for this action as proper in the District of Delaware pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) is not contested.
 - 8. This Court's personal jurisdiction over the parties is not contested.

II. THE ACCUSED PRODUCT

- 9. Labcorp accuses the SignateraTM test of infringing the Asserted Patents ("Accused Product" or "Signatera").
- 10. The software that performs the allegedly infringing method is called TNseq and is sold by Sentieon, Inc.
- 11. Portions of the source code for TNseq have been produced in this action bearing the Bates number SENTIEONSOURCECODE00001, which the parties agree qualifies as a business record and is admissible at trial.
- 12. Labcorp does not accuse any other Natera product of infringing the Asserted Patents.

III. THE ASSERTED PATENTS

A. The '799 Patent

- 13. The '799 Patent is titled "Sequence Assembly."
- 14. The application for the '799 Patent, Appl. No. 14/250,891 ("'891 Application"), was filed on April 11, 2014 and is a continuation of U.S. Pat. Appl. No. 13/494,616, filed June 12, 2012, which issued as U.S. Patent No. 8,738,300 (the "'300 Patent"), which is a continuation of

- U.S. Pat. Appl. No. 13/439,508, filed on April 4, 2012 and which issued as U.S. Patent No. 8,209,130 (the "'130 Patent").
- 15. The inventors named on the face of the '799 Patent are Gregory Porreca and Caleb Kennedy.
- 16. Gregory Porreca and Caleb Kennedy are both former employees of Good Start Genetics, Inc. ("Good Start Genetics").
- 17. Gregory Porreca is the founder and CEO of Molecular Loop Biosolutions, LLC ("Molecular Loop").
 - 18. The '799 Patent issued on March 31, 2020.
 - 19. The assignee listed on the face of the '799 Patent is Molecular Loop.
- 20. Molecular Loop assigned its rights in the '799 Patent to Invitae under a Patent Assignment Agreement executed on March 13, 2021 in connection with an Asset Purchase Agreement executed on March 13, 2021.
- 21. Invitae was the sole owner of, and holder of, all substantial rights in the '799 Patent at the time it filed the complaints in this case. Subsequently, Labcorp acquired all substantial rights in the '799 Patent and now has sole ownership of the '799 Patent.

B. The '308 Patent

- 22. The '308 Patent is titled "Sequence Assembly."
- 23. The application for the '308 Patent, U.S. Patent Appl. No. 17/322,610, was filed on May 17, 2021 and is a continuation of U.S. Patent Appl. No. 16/790,519, filed on February 13, 2020, which is a continuation of the '891 Application, which issued as the '799 Patent and claims priority to Appl. No. 13/494,616, filed June 12, 2012 and which issued as the '300 Patent, and Appl. No. 13/439,508, filed on April 4, 2012 and which issued as the '130 Patent.

- 24. The named inventors of the '308 Patent are Gregory Porreca and Caleb Kennedy.
- 25. The '308 Patent issued on October 19, 2021.
- 26. The assignee listed on the face of the '308 Patent is Invitae Corporation.
- 27. Invitae was the sole owner of, and holder of, all substantial rights in the '308 Patent at the time it filed the complaints in this case. Subsequently, Labcorp acquired all substantial rights in the '308 Patent and now has sole ownership of the '308 Patent.

C. The '863 Patent

- 28. The '863 Patent is titled "Sequence Assembly."
- 29. The application for the '863 Patent, U.S. Patent Appl. No. 17/322,587, was filed on May 17, 2021 and is a continuation of U.S. Patent Appl. No. 16/790,519, filed on February 13, 2020, which is a continuation of the '891 Application, which issued as the '799 Patent and claims priority to Appl. No. 13/494,616, filed June 12, 2012, and which issued as the '300 Patent, and Appl. No. 13/439,508, filed on April 4, 2012, and which issued as the '130 Patent.
- 30. The inventors named on the face of the '863 Patent are Gregory Porreca and Caleb Kennedy.
 - 31. The '863 Patent issued on October 26, 2021.
 - 32. The assignee listed on the face of the '863 Patent is Invitae Corporation.
- 33. Invitae was the sole owner of, and holder of, all substantial rights in the '863 Patent at the time it filed the complaints in this case. Subsequently, Labcorp acquired all substantial rights in the '863 Patent and now has sole ownership of the '863 Patent.

IV. CLAIM CONSTRUCTION

34. On October 18, 2022, the Court construed the terms below to have the following meanings (D.I. 84, 85)¹:

Claim Term	Court's Construction	
Court's Construction		
"sequence reads"	raw reads as generated by the sequencing instrument	
"a plurality of sequence reads" ('799 Patent)	"sequence reads" to be defined as above, no	
"the plurality of sequence reads" ('863 Patent)	other construction necessary	
"the sequence reads" ('308 Patent)		
"said plurality of sequence reads" ('799 Patent)	"sequence reads" to be defined as above, no other construction necessary	
"the plurality of sequence reads" ('799 Patent)		
"contig:reference descriptions of mutations" ('799 Patent)	a description of a mutation in a contig as it exists in the nucleic acid with reference to the genome	
"contig-to-reference descriptions of mutations ('863 Patent)		
"reference alignment(s)" ('308 Patent)	placement in a reference genome	
"read:contig descriptions" ('799 Patent)	a description of a sequence read with reference to a contig	
"read-to-contig descriptions" ('863 Patent)		
"sequence read alignments" ('308 Patent)	placements of sequence reads	
"read:reference descriptions" ('799 Patent)	description of a sequence read with reference to the reference genome	
"read-to-reference descriptions" ('863 Patent)	to the reference genome	
"combining the contig:reference descriptions with the read:contig descriptions" ('799 Patent)	No construction necessary. Plain and ordinary meaning.	

¹ Unless stated otherwise, citations to docket numbers refer to Case No. 21-cv-669-GBW.

"combining the reference alignment and the sequence read alignment" ('308 Patent)	
Agreed-Upon Construction	
"genotyping" ('308 Patent)	assigning a genotype to

V. FACTS PERTAINING TO INVALIDITY

- 35. The following documents and materials are admissible evidence at trial and are business records and were available to the public as of the specified dates (except the public availability of the source code for version 1.8.2 of CASAVA):
- The source code for version 1.8.2 of Illumina's CASAVA software program, produced as ILLUMINA-0008568 and ILLUMINA-0008569;
- The Complete Secondary Analysis Workflow for the Genome Analyzer Technical Note, produced as ILLUMINA-0000988 and ILLUMINA-0003413, which was publicly available no later than October 2009;
- The GenomeStudio Software DNA Sequencing Module Workflow Technical Note, produced as ILLUMINA-0000987, which was publicly available no later than January 2009;
- The CASAVA v.1.8 Changes document, produced as ILLUMINA-0001185, which was publicly available no later than September 2011;
- The CASAVA 1.8.2 Release Notes document, produced as ILLUMINA-0002642, which was publicly available no later than September 2011;
- The Genome Analyzer Pipeline Software User Guide, produced as ILLUMINA-0002650, which was publicly available no later than January 2009;

- The CASAVA 1.8.2 Quick reference Guide, produced as ILLUMINA-0004065 and ILLUMINA-0005041, which was publicly available no later than October 2011;
- The CASAVA v.1.8.2 User Guide, produced as ILLUMINA-0004093 and ILLUMINA-0003123, which was publicly available no later than December 2011;
- The Improved Accuracy for ELAND and Variant Calling document, produced as ILLUMINA-0008542, which was publicly available no later than October 2011;
- The "From reads to results: alignment and analysis of NextGen sequence data" document, produced as ILLUMINA-0008550, which was publicly available no later than October 2009; and
- The CASAVA User Guide, produced as NTRA-INVT-00000891, which was publicly available no later than May 2011.
- 36. The prior art reference Li_2008_samtools.pdf Li et al., *Mapping short DNA* sequencing reads and calling variants using mapping quality scores, GENOME RESEARCH 18(11):1851–1858 (2008) ("Li, Ruan, & Durbin (2008)") is admissible and was publicly available as of August 19, 2008, and was produced bearing the Bates number Invitae0010119541–Invitae0010119549.
- 37. The prior art reference Li and Durbin, *Fast and accurate short read alignment with Burrows-Wheeler transform*, BIOINFORMATICS 25:1754-1760 (2009) ("Li and Durbin") is admissible and was publicly available as of May 18, 2009, and was produced bearing the Bates number Invitae0010122662–Invitae0010122668.
- 38. The prior art reference Albers et al., *Dindel: Accurate indel calls from short-read data*, GENOME RESEARCH 21:961-973 (2011) ("Albers (2011)") is admissible and was publicly

available as of October 27, 2010, and was produced bearing the Bates number NTRA-INVT-00000719-NTRA-INVT-00000733.

- 39. The prior art reference Albers et al., *Dindel: Accurate indel calls from short-read data*, GENOME RESEARCH 21:961-973 (2011) Supplementary Information ("Albers (2011) Supplementary Information") is admissible and was publicly available as of October 27, 2010, and was produced bearing the Bates number NTRA-INVT-00000734—NTRA-INVT-00000746.
- 40. The prior art reference Birol et al., *De novo transcriptome assembly with ABySS*, BIOINFORMATICS 25:2872–2877 (2009) ("Birol (2009)") is admissible and was publicly available as of June 15, 2009, and was produced bearing the Bates number NTRA-INVT-00000830–NTRA-INVT-00000835.
- 41. The prior art reference Chiu et al., Trans-AbySS v1.2.0: User Manual (2011) ("Trans-ABySS User Manual") is admissible and was publicly available as of January 7, 2011, and was produced bearing the Bates number NTRA-INVT-00001105–NTRA-INVT-00001136.
- 42. The prior art reference Craig et al., *Identification of genetic variants using bar-coded multiplexed sequencing*, NATURE METHODS 5:887–893 (2008) ("Craig (2008)") is admissible and was publicly available as of September 14, 2008, and was produced bearing the Bates number NTRA-INVT-00001151–NTRA-INVT-00001166.
- 43. The prior art reference DePristo et al., *A framework for variation discovery and genotyping using next- generation DNA sequencing data*, NATURE GENETICS 43:491-498 (2011) ("DePristo (2011)") is admissible and was publicly available as of April 10, 2011, and was produced bearing the Bates number NTRA-INVT-00001186–NTRA-INVT-00001205.

- 44. The prior art reference DePristo et al., *A framework for variation discovery and genotyping using next generation DNA sequencing data*, NATURE GENETICS 43:491-498 (2011), Supplemental Information ("DePristo (2011) Supplemental Information") is admissible and was publicly available as of April 10, 2011, and was produced bearing the Bates number NTRA-INVT-00001206–NTRA-INVT-00001223.
- 45. The prior art reference DePristo et al., *A framework for variation discovery and genotyping using next-generation DNA sequencing data*, NATURE GENETICS 43:491-498 (2011) Online Methods ("DePristo (2011) Online Methods") is admissible and was publicly available as of April 10, 2011, and was produced bearing the Bates number NTRA-INVT-00001224–NTRA-INVT-00001233.
- 46. The prior art reference Etter, P. et al., *Local De Novo Assembly of RAD Paired-End Contigs Using Short Sequencing Reads*, PLoS ONE 6(4):e18561, (2011) ("Etter (2011)") is admissible and was publicly available as of April 13, 2011, and was produced bearing the Bates number NTRA-INVT-00001283–NTRA-INVT-00001292.
- 47. The prior art reference Etter, P. et al., *Local De Novo Assembly of RAD Paired-End Contigs Using Short Sequencing Reads*, PLoS ONE 6(4):e18561, (2011) Supplemental Information ("Etter (2011)" Supplemental Information) is admissible and was publicly available as of April 13, 2011, and was produced bearing the Bates number NTRA-INVT-00001293–NTRA-INVT-00003907.
- 48. The prior art reference Etter, P. et al., *Local De Novo Assembly of RAD Paired-End Contigs Using Short Sequencing Reads*, PLoS ONE 6(4):e18561, (2011) Supplemental Information -TXT ("Etter (2011) Supplemental Information TXT") is admissible and was

publicly available as of April 13, 2011, and was produced bearing the Bates number NTRA-INVT-00003908–NTRA-INVT-00007528.

- 49. The prior art reference Frith et al., *Parameters for accurate genome alignment*, BMC BIOINFORMATICS 11(80):1-14 (2010) ("Frith (2010)") is admissible and was publicly available as of February 9, 2010, and was produced bearing the Bates number NTRA-INVT-00007959–NTRA-INVT-00007972.
- 50. The prior art reference Genome Analyzer System, Illumina® Sequencing (2009) ("Illumina Genome Analyzer (2009)") is admissible and was publicly available as of May 4, 2009, and was produced bearing the Bates number NTRA-INVT-00007982–NTRA-INVT-00007985.
- 51. The prior art reference George et al., *Trans genomic capture and sequencing of primate exomes reveals new targets of positive selection*, GENOME RESEARCH 21: 1686–1694 (2011) ("George (2011)") is admissible and was publicly available as of July 27, 2011, and was produced bearing the Bates number NTRA-INVT-00007993–NTRA-INVT-00008002.
- 52. The prior art reference George et al., *Trans genomic capture and sequencing of primate exomes reveals new targets of positive selection*, GENOME RESEARCH 21: 1686–1694 (2011) Supplemental Information ("George (2011) Supplemental Information") is admissible and was publicly available as of July 27, 2011, and was produced bearing the Bates number NTRA-INVT-00008003–NTRA-INVT-00008033.
- 53. The prior art reference HiSeqTM 2000 sequencing system, *Redefining the trajectory* of sequencing, Specifications Sheet: Illumina® Sequencing (2010) ("Illumina HiSeq (2010) Specification Sheet") is admissible and was publicly available as of July 17, 2010, and was produced bearing the Bates number NTRA-INVT-00008063–NTRA-INVT-00008066.

- 54. The prior art reference Illumina, *De novo assembly using Illumina reads*, Technical Note Illumina Sequencing (2009) ("Illumina Technical Note") is admissible and was publicly available as of October 12, 2009, and was produced bearing the Bates number NTRA-INVT-00008110–NTRA-INVT-00008118.
- 55. The source code file IndelRealigner.java ("IndelRealigner") is admissible and was publicly available as of June 28, 2010, and was produced bearing the Bates number NTRA-INVT-00008163–NTRA-INVT-00008194.
- 56. The prior art reference LeVan et al., *ChiP-seq analysis of SOLiD*TMsequence reads with NextGENeTM software, SOFTGENETICS (2008) ("LeVan (2008)") is admissible and was publicly available as of September 2008, and was produced bearing the Bates number NTRA-INVT-00008421–NTRA-INVT-00008424.
- 57. The prior art reference Li et al., *De novo assembly of human genomes with massively parallel short read sequencing*, GENOME RESEARCH 20:265-272 (2010) ("Li (2009)") is admissible and was publicly available as of December 17, 2009, and was produced bearing the Bates number NTRA-INVT-00008457–NTRA-INVT-00008477.
- 58. The prior art reference Li, H. and Homer, N., *A survey of sequence alignment algorithms for next-generation sequencing*, Briefings in Bioinformatics, 11(5):473-83 (2010) ("Li & Homer (2010)") is admissible and was publicly available as of May 11, 2010, and was produced bearing the Bates number NTRA-INVT-00008485–NTRA-INVT-00008495.
- 59. The prior art reference Li et al., *The sequence alignment/map format and SAMtools*, BIOINFORMATICS 25:2078-2079 (2009) ("Durbin (2009)") is admissible and was publicly

available as of June 8, 2009, and was produced bearing the Bates number NTRA-INVT-00008516-NTRA-INVT-00008517.

- 60. The prior art reference Manion, M. et al., *Deep sequencing analysis and low frequency SNP/Mutation detection with NextGENe Software*, NextGENe™ by SoftGenetics (2009) ("Manion (April 2009)") is admissible and was publicly available as of April 2009, and was produced bearing the Bates number NTRA-INVT-00008534–NTRA-INVT-00008537.
- 61. The prior art reference Manion, M. et al., Sequence Analysis Using Barcode/Index Tags of Pooled Samples with NextGENe Software, NextGENe™ by SoftGenetics (2009) ("Manion (March 2009)") is admissible and was publicly available as of March 2009, and was produced bearing the Bates number NTRA-INVT-00008538–NTRA-INVT-00008540.
- 62. The prior art reference McKenna et al., *The Genome Analysis Toolkit: A MapReduce framework for analyzing next-generation DNA sequencing data*, Genome Research 20(9):1297-1303 (2010) ("McKenna (2010)") is admissible and was publicly available as of July 19, 2010, and was produced bearing the Bates number NTRA-INVT-00008591–NTRA-INVT-00008598.
- 63. The prior art reference Metzker, Sequencing technologies the next generation, NATURE REVIEWS GENETICS 11:31-46 (2010) ("Metzker (2010)") is admissible and was publicly available as of December 8, 2009, and was produced bearing the Bates number NTRA-INVT-00008599–NTRA-INVT-00008614.
- 64. The prior art reference Miller, J., et al., *Assembly algorithms for next-generation sequencing data*, Genomics, 95, 315-327 (2010) ("Miller (2010)") is admissible and was publicly

available as of March 6, 2010, and was produced bearing the Bates number NTRA-INVT-00008633-NTRA-INVT-00008645.

- 65. The prior art reference Morin, R. et al., *Frequent mutation of histone-modifying genes in non-Hodgkin lymphoma*, Nature 476(7360):298-303 (2011) ("Morin (2011)") is admissible and was publicly available as of July 27, 2011, and was produced bearing the Bates number NTRA-INVT-00008646–NTRA-INVT-00008651.
- 66. The prior art reference Morin, R. et al. (2011) Supplemental Information ("Morin (2011) Supplemental Information") is admissible and was publicly available as of July 27, 2011, and was produced bearing the Bates number NTRA-INVT-00008652–NTRA-INVT-00008703.
- 67. The source code file RealignerTargetCreator.java ("RealignerTargetCreator") is admissible and was publicly available as of June 28, 2010, and was produced bearing the Bates number NTRA-INVT-00008926–NTRA-INVT-00008932.
- 68. The prior art reference Reinhardt, J. et al., *De novo assembly using low-coverage short read sequence data from the rice pathogen Pseudomonas syringae pv. oryzae*, Genome Research 19:294-305 (2009) ("Reinhardt (2009)") is admissible and was publicly available as of November 17, 2008, and was produced bearing the Bates number NTRA-INVT-00008933–NTRA-INVT-00008951.
- 69. The prior art reference Reinhardt et al. (2009) Supplemental Information ("Reinhardt (2009) Supplemental Information") is admissible and was publicly available as of November 17, 2008, and was produced bearing the Bates number NTRA-INVT-00008952–NTRA-INVT-00008958.

- 70. The prior art reference Robertson, G., et al., *De novo assembly and analysis of RNA-seq data*, NATURE METHODS 7:909-912 (2010) ("Robertson (2010)"), is admissible and was publicly available as of October 10, 2010, and was produced bearing the Bates number NTRA-INVT-00008959–NTRA-INVT-00008965.
- 71. The prior art reference Robertson et al., *De novo assembly and analysis of RNA-seq data*, NATURE METHODS 7:909-912 (2010) Supplemental Information ("Robertson (2010) Supplemental Information") is admissible and was publicly available as of October 10, 2010, and was produced bearing the Bates number NTRA-INVT-00008966–NTRA-INVT-00009000.
- 72. The prior art reference Schwartz, T., et al., *A garter snake transcriptome:* pyrosequencing, de novo assembly, and sex specific differences, BMC Genomics 11 (694) (2010) ("Schwartz (2010)") is admissible and was publicly available as of December 7, 2010, and was produced bearing the Bates number NTRA-INVT-00009036–NTRA-INVT-00009052.
- 73. The prior art reference Simpson, J., et al., *ABySS: A parallel assembler for short read sequence data*, GENOME RESEARCH 19: 1117–1123 (2009) ("Simpson (2009)") is admissible and was publicly available as of February 27, 2009, and was produced bearing the Bates number NTRA-INVT-00009065–NTRA-INVT-00009072.
- 74. The prior art reference Simpson, J., et al., *ABySS: A parallel assembler for short read sequence data*, GENOME RESEARCH 19: 1117–1123 (2009) Supplemental Materials ("Simpson (2009) Supplemental Materials") is admissible and was publicly available as of February 27, 2009, and was produced bearing the Bates number NTRA-INVT-00009096–NTRA-INVT-00009111.

- 75. The prior art reference U.S. Patent No. 6,138,077 (Brenner) Method, Apparatus and Computer Program Product for Determining a Set of Non-Hybridizing Oligonucleotides ("Brenner '077") is admissible and was filed June 3, 1998, and issued and was publicly available as of October 24, 2000, and was produced bearing the Bates number NTRA-INVT-00009211–NTRA-INVT-00009246.
- 76. The prior art reference U.S. Patent No. 8,271,206 (Liu et al.) DNA Sequence Assembly Methods of Short Reads ("Liu (2009)") is admissible and was filed April 21, 2009, and issued and was publicly available as of September 18, 2012, and was produced bearing the Bates number NTRA-INVT-00009318–NTRA-INVT-00009367.
- 77. The prior art reference Warren, R., et al., *Assembling millions of short DNA sequences using SSAKE*, Bioinformatics 23:500-501 (2007) ("Warren (2007)") is admissible and was publicly available as of December 8, 2006, and was produced bearing the Bates number NTRA-INVT-00009934–NTRA-INVT-00009956.
- 78. The prior art reference Wiseman, R., et al., *Major histocompatibility complex genotyping with massively parallel pyrosequencing*, NATURE MEDICINE 15:1322-1326 (2009) ("Wiseman (2009)"), is admissible and was publicly available as of October 11, 2009, and was produced bearing the Bates number NTRA-INVT-00009951–NTRA-INVT-00009956.
- 79. The prior art reference WO 2011/160206 A1 (Morin, R. et al.) Biomarkers for Non-Hodgkin Lymphomas and Uses Thereof ("WO '206") is admissible and was filed June 23, 2011, and was issued and was publicly available as of December 29, 2011, and was produced bearing the Bates number NTRA-INVT-00010144–NTRA-INVT-00010240.

- 80. The prior art reference Zerbino, D. and Birney, E., *Velvet: Algorithms for de novo short read assembly using de Bruijn graphs*, Genome Research 18:821–829 (2008) ("Zerbino (2008)") is admissible and was publicly available as of March 18, 2008, and was produced bearing the Bates number NTRA-INVT-00010232–NTRA-INVT-00010240.
- 81. The source code for the GATK software package that is available as supplemental data to McKenna (2010), produced with the filename GATK_source_6_28=2010.tar.gz ("McKenna (2010) Supplemental Source Code," or "GATK Version 1") is admissible and was publicly available as of June 28, 2010, and was produced bearing the Bates number NTRA-INVT-00310548.
- 82. The source code for the first version of HaplotypeCaller ("HaplotypeCaller (2011)"), produced with the native filename gatk_privateGitArchive_08-24-2011.tar, is admissible and was produced bearing the Bates number NTRA-INVT-00358917–NTRA-INVT-00359487.
- 83. The prior art reference Illumina sequencing, *Multiplexed sequencing with the Illumina Genome Analyzer System* ("Illumina Multiplexed Sequencing (2008)") is admissible and was publicly available as of December 2, 2008, and was produced bearing the Bates number NTRA-INVT-00414242–NTRA-INVT-00414245.
- 84. The prior art reference Schneeberger, K. et al., *Reference-guided assembly of four diverse Arabidopsis thaliana genomes*, Proceedings of the National Academy of Sciences 108(25):10249–10254 (2011) ("Schneeberger (2011)") is admissible and was publicly available as of June 6, 2011, and was produced bearing the Bates number NTRA-INVT-00414896–NTRA-INVT-00414901.

- 85. The prior art reference Schneeberger, K. et al., *Reference-guided assembly of four diverse Arabidopsis thaliana genomes*, Proceedings of the National Academy of Sciences 108(25):10249–10254 (2011) Supporting Information ("Schneeberger (2011) Supporting Information") is admissible and was publicly available as of June 6, 2011, and was produced bearing the Bates number NTRA-INVT-00414246–NTRA-INVT-00414254.
- 86. The prior art reference Albers, Dindel User Guide, version 1.0 (2010) ("Dindel User Guide") is authentic and admissible and was publicly available as of October 26, 2010, and was produced bearing the Bates number NTRA-INVT-00414265–NTRA-INVT-00414280.
- 87. The prior art reference Mayer, *Bioinformatics for Omics Data*, Methods in Molecular Biology (2011) ("Mayer (2011)") is admissible and was publicly available as of March 3, 2011, and was produced bearing the Bates number NTRA-INVT-00414318– NTRA-INVT-00414895.
- 88. Source code for the software program Trans-ABySS ("Trans-ABySS Source Code") is admissible and was publicly available as of January 7, 2011, and was produced bearing the Bates number NTRA-INVT-00414915–NTRA-INVT-00415498.
- 89. The source code for the 2012 version of HaplotypeCaller ("HaplotypeCaller (2012)") that was included in the GATK 2.0 software package is admissible and was publicly available as of July 24, 2012, and was produced bearing the Bates number NTRA-INVT-00415528–NTRA-INVT-00419832.
- 90. The prior art reference Altschul et al., *Basic local alignment search tool*, Journal of Molecular Biology 215(3):403-410 (1990) ("Altschul (1990)") is admissible and was publicly

available as of October 5, 1990, and was produced bearing the Bates number NTRA-INVT-00430298-NTRA-INVT-00430305.

- 91. The prior art reference Ning et al., SSAHA: A Fast Search Method for Large DNA Databases, Genome Research 11:1725-1729 (2001) ("Ning (2001)") is admissible and was publicly available as of October 2001 and was produced bearing the Bates number NTRA-INVT-00432574–NTRA-INVT-00432579.
- 92. The prior art reference Willing et al., *Paired-end RAD-seq for de novo assembly and marker design without available reference*, BIOINFORMATICS 27:2187-2193 (2011) ("Willing (2011)") is admissible and was publicly available as of June 27, 2011, and was produced bearing the Bates number NTRA-INVT-00433184–NTRA-INVT-00433190.
- 93. The prior art reference Kurtz et al., *Versatile and open software for comparing large genomes*, Genome Biology 5(R12) (2004) ("Kurtz (2004)") is admissible and was publicly available as of January 30, 2004, and was produced bearing the Bates number NTRA-INVT-00433191–NTRA-INVT-00433199.
- 94. The prior art reference Margulies et al., *Genome sequencing in microfabricated high-density picolitre reactors*, NATURE 437:376-380 (2005) ("Margulies (2005)") is admissible and was publicly available as of July 31, 2005, and was produced bearing the Bates number NTRA-INVT-00431705–NTRA-INVT-00431710.
- 95. The prior art reference Johnson et al., *NCBI BLAST: a better web interface*, Nucleic Acids Research 36:W5-W9 (2008) ("Johnson (2008)") is admissible and was publicly available as of April 24, 2008, and was produced bearing the Bates number NTRA-NVT-00430315–NTRA-NVT-00430319.

- 96. The prior art reference Myllykangas and Hnlee Ji, *Targeted deep resequencing of the human cancer genome using next-generation technologies*, Biotechnol. Genet. Eng'g. Rev. 27:135-158 (2010) ("Myllykangas (2010)") is admissible and was publicly available as of 2010, and was produced bearing the Bates number NTRA-INVT-00432549–NTRA-INVT-00432573.
- 97. The prior art reference Schedule for Workshop I: Next-Generation Sequencing Technology and Algorithms for Primary Data Analysis, CONFERENCE OF THE INSTITUTE FOR PURE & APPLIED MATHEMATICS (October 3–6, 2011) ("Next-Generation Sequencing Workshop") is admissible and was publicly available as of October 6, 2011, and was produced bearing the Bates number NTRA-INVT-00432440–NTRA-INVT-00432445.
- 98. The prior art reference Manske and Kwiatkowski, *LookSeq: A browser-based viewer for deep sequencing data*, Genome Research 19:2125-2032 (2009) ("Manske (2009)") is admissible and was publicly available as of August 13, 2009, and was produced bearing the Bates number NTRA-INVT-00008541–NTRA–INVT-00008548.
- 99. The prior art reference Danecek et al., *The variant call format and VCFtools*, Bioinformatics, 27(15):2156-2158 (2011) ("Danecek (2011)") is admissible and was publicly available as of June 7, 2011, and was produced bearing the Bates number NTRA-INVT-00430320–NTRA-INVT-00430322.
- 100. The prior art reference Wiesner et al., *Germline mutations in BAP1 predispose to melanocytic tumors*, Nat Genet. 43(10):1018-1021 (2011) ("Wiesner (2011)") is admissible and was publicly available as of August 28, 2011, and was produced bearing the Bates number NTRA-INVT-00431711-NTRA-INVT-00431715.

- 101. The prior art reference Li et al., *SOAP: short oligonucleotide alignment program*, BIOINFORMATICS 24:713–714 (2008) ("Li (2008)") is admissible and was publicly available as of January 28, 2008.
- 102. The prior art reference Li and Durbin, *Fast and accurate long-read alignment with Burrows-Wheeler Transform*, BIOINFORMATICS 26:589-595 (2010) ("Li & Durbin (2010)") is admissible and was publicly available as of January 15, 2010.
- 103. The prior art reference Lukashin, et al., *GeneMark.hmm: New solutions for gene finding*, NUCLEIC ACIDS RESEARCH 26(4):1107–1115 (1998) ("Lukashin (1998)") is admissible and was publicly available as of February 15, 1998.

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION AMERICA HOLDINGS,	ON OF)
Plaintiff,)) C.A. No. 21-669 (GBW)
V.)
NATERA, INC.,	<i>)</i>)
Defendan	t.)
LABORATORY CORPORATION AMERICA HOLDINGS,	ON OF)
Plaintiff,) C.A. No. 21-1635 (GBW)
V.)
NATERA, INC.,)
Defendan	t.)

EXHIBIT 2: PLAINTIFF LABCORP CORPORATION'S STATEMENT OF FACTS
THAT REMAIN TO BE LITIGATED

Pursuant to Delaware Local Rule 16.3(c)(4), Plaintiff Laboratory Corporation of America Holdings ("Labcorp") hereby submits the following statement of issues of fact that remain to be litigated.

This statement is based on the current status of the case and Court's rulings to date. Labcorp reserves the right to revise, amend, supplement, or modify the following statement based on any pretrial ruling by the Court and/or to address any additional issues, arguments, evidence, or other developments in the case, including edits to the draft pretrial order, any meet and confers or other negotiations between the parties, pending motions, and Defendant's identification of issues of law and fact to be litigated or any new issues Defendant may raise, or for other good cause. Labcorp does not assume the burden of proof with regard to any of the below-listed issues of facts. Further details regarding these issues have been explained at length in Labcorp's pleadings and discovery responses, including in its contentions, interrogatory responses, expert reports, by experts at depositions and by fact witnesses at depositions, which Labcorp incorporates by reference. Should the Court determine that any issue identified in this list is more properly considered an issue of law, it shall be so considered and Labcorp incorporates such issue into Labcorp's Statement of Issues of Law That Remain to be Litigated (Ex. 4 to Proposed Final Pretrial Order). To the extent that Labcorp's Statement of Issues of Law That Remain to be Litigated contains issues that the Court deems to be issues of fact, those issues are incorporated herein by reference. The following statement of issues of fact is not exhaustive and Labcorp reserves the right to prove any matters identified in the pleadings and discovery responses, including in its contentions, expert reports, by experts at depositions, and by fact witnesses at depositions. Labcorp intends to offer evidence as to the issues of fact and issues of law identified in this Pretrial Order. Labcorp further intends to offer evidence to rebut evidence offered by Defendant.

I. ISSUES ON WHICH LABCORP BEARS THE BURDEN OF PROOF

A. Infringement

- 1. Whether Labcorp can prove by a preponderance of the evidence that the use of the Signatera Accused Products perform each step of the '799 Patent Asserted Claims.
- 2. Whether Labcorp can prove by a preponderance of the evidence that Defendant directly infringes the '799 Patent Asserted Claims by using the Signatera Accused Products in an infringing manner.
- 3. Whether Labcorp can prove by a preponderance of the evidence that the use of the Signatera Accused Products perform each step of the '308 Patent Asserted Claims.
- 4. Whether Labcorp can prove by a preponderance of the evidence that Defendant directly infringes the '308 Patent Asserted Claims by using the Signatera Accused Products in an infringing manner.
- 5. Whether Labcorp can prove by a preponderance of the evidence that the use of the Signatera Accused Products perform each step of the '863 Patent Asserted Claims.
- 6. Whether Labcorp can prove by a preponderance of the evidence that Defendant directly infringes the '863 Patent Asserted Claims by using the Signatera Accused Products in an infringing manner.

B. Remedies

7. The amount of damages in lost profits that Labcorp is owed from Defendant due to Defendant's infringement of one or more of the Asserted Claims of the Patents-In-Suit through the date of the verdict.

- 8. The amount of damages in reasonable royalties that Labcorp is owed from Defendant due to Defendant's infringement of one or more of the Asserted Claims of the Patents-In-Suit through the date of the verdict.
- 9. Whether Labcorp is entitled to a permanent injunction, enjoining Defendant and its officers, directors, employees, agents, servants, affiliates, and/or all persons in active concert or participation with it from continued infringement of the Patents-In-Suit, prior to the expiration of the patents, pursuant to 35 U.S.C. § 283.
- 10. Whether Labcorp has established that this is an exceptional case and that it is entitled to an award of attorneys' fees and costs under 35 U.S.C. § 285, and if so, the amount.
- 11. Whether Labcorp is entitled to an award of prejudgment and post-judgment interest, and if so, the amounts.

II. RESPONSE TO DEFENDANT'S STATEMENT OF CONTESTED FACTS FOR ISSUES ON WHICH DEFENDANTS BEAR THE BURDEN OF PROOF

A. Validity

- 12. Whether Defendant can prove by clear and convincing evidence that any of the Asserted Claims of the Patents-in-Suit are invalid as patent ineligible under 35 U.S.C. § 101, including whether any of the Asserted Claims of the Patents-in-Suit are directed to an abstract idea and/or whether any of the Asserted Claims of the Patents-in-Suit contain an inventive concept or merely well-understood, routine, and/or conventional activities, steps, or elements. ¹
- 13. Whether Defendant can prove by clear and convincing evidence that any of the Asserted Claims of the Patents-in-Suit are invalid as anticipated under 35 U.S.C. § 102, including

¹ Labcorp objects to Defendant's statement of the patentable subject matter issue as an issue that remains to be litigated at the jury trial. This issue has already been resolved by the Court, finding the claims were not directed to an abstract idea under *Alice* step one. Dkt. No. 28.

whether the prior art asserted against any of the Asserted claims of the Patents-in-Suit qualifies as prior art under pre-AIA 35 U.S.C. §§ 102(a), 102(b), 102(e), and/or 102(g) and whether the asserted prior art discloses each and every element of the claims.

- 14. Whether Defendants can prove by clear and convincing evidence that any of the Asserted Claims of the Patents-in-Suit are invalid as obvious under 35 U.S.C. § 103, including issues of the level of ordinary skill in the art at the time of the alleged invention of the Asserted Claims of the Patents-in-Suit, the scope and content of the asserted prior art, and the differences between the claimed invention of the Asserted Claims of the Patents-in-Suit and the asserted prior art.
- 15. Whether the secondary considerations of non-obviousness demonstrate that the Asserted Claims of the Patents-in-Suit would not have been obvious.
- 16. Whether Defendant can prove by clear and convincing evidence that any of the Asserted Claims of the Patents-in-Suit are invalid for failure to satisfy the enablement requirement under 35 U.S.C. § 112, including whether the Patents-in-Suit teach those of ordinary skill in the art how to make and use the full scope of the claimed invention without undue experimentation.
- Asserted Claims of the Patents-in-Suit are invalid for failure to satisfy the written description requirement under 35 U.S.C. § 112, including whether the Patents-in-Suit describe the full scope of the claimed invention in sufficient detail so that they reasonably convey to one of ordinary skill in the art that the named inventors had possession of the claimed subject matter as of the filing date.
- 18. Whether Defendant can show by clear and convincing evidence that any of the Asserted Claims of the '799 Patent are invalid for failure to satisfy the definiteness requirement

under 35 U.S.C. § 112, including whether the claims, read in light of the specification and the prosecution history, fail to inform, with reasonable certainty, a person of ordinary skill in the art about the scope of the alleged invention.².

B. Defendant's Alleged Remedies³

- 19. Whether this is an exceptional case justifying an award of attorneys' fees under 35U.S.C. § 285, including interest.
 - 20. Whether Labcorp is entitled to attorneys' fees, costs, and litigation expenses.
 - 21. Whether Labcorp is entitled to any other relief that the Court deems just and proper.

² Labcorp objects to Defendant's statement of the definiteness issue as a contested fact that remains to be litigated at the jury trial. "A determination of claim definiteness is a question of law." *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 705 (Fed. Cir. 1998). *See also Atmel Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374, 1378 (Fed. Cir. 1999) ("Indefiniteness, therefore, like claim construction, is a question of law that we review *de novo.*"); *Nature Simulation Sys. Inc. v. Autodesk, Inc.*, 50 F.4th 1358, 1360 (Fed. Cir. 2022).

³ Defendant bears the burden of proving it is entitled to any alleged remedies, including whether it is entitled to costs and attorneys' fees under 35 U.S.C. § 285. Labcorp, to the extent necessary, will introduce evidence to rebut Defendant's assertion that it is entitled to any remedies, including whether it is entitled to costs and attorneys' fees under 35 U.S.C. § 285.

EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

C.A. No. 21-cv-669-GBW

C.A. No. 21-cv-1635-GBW

EXHIBIT 3: DEFENDANT'S STATEMENT OF ISSUES OF FACT THAT REMAIN TO BE LITIGATED

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Exhibit 3

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Exhibit 3

Natera respectfully submits the following statement of issues of fact that remain to be litigated. This statement is based on Natera's claims, counterclaims, and defenses, Natera's current understanding of Plaintiff's claims and defenses, and the proceedings in this action to date. Should the Court determine that any issue identified in this list is more properly considered an issue of law, it shall be so considered and Natera incorporates such issue into Natera's Statement of Issues of Law That Remain to Be Litigated (Ex. 5 to Proposed Final Pretrial Order). To the extent that Natera's Statement of Issues of Law That Remain to Be Litigated contains issues that the Court deems to be issues of fact, those issues are incorporated herein by reference. Natera reserves the right to revise, modify, supplement, or change the issues of fact to be litigated in response to subsequent Court rulings and/or Labcorp's identification of issues of law and fact to be litigated or any new issues Labcorp may raise, or for other good cause. The following statement of issues of fact is not exhaustive and Natera reserves the right to prove any matters identified in the pleadings and discovery responses, including in its contentions, expert reports, by experts at depositions, and by fact witnesses at depositions. Natera further intends to offer evidence to rebut evidence offered by Labcorp. The following issues are identified insofar as they are issues of fact or involve underlying issues of fact. By identifying the following issues, Natera does not necessarily concede that each of these issues, in whole or in part, is a pure issue of fact. By identifying the following issues, Natera does not necessarily concede that any of these issues, in whole or in part, is a material fact as to which there is any genuine dispute. Further, insofar as the following issues, as a matter of law and precedent, themselves turn on additional or subsidiary factual issues or elements, those factual issues or elements are incorporated.

I. <u>INVALIDITY OF THE ASSERTED PATENTS</u>

A. Invalidity of the '799 Patent

- 1. Whether or not Labcorp has proven the date to which it is entitled to claim priority for the Asserted Claims of the '799 Patent.
- 2. Whether or not Labcorp has proven the date on which the alleged invention claimed by the Asserted Claims of the '799 Patent was conceived.
- 3. Whether or not Labcorp has proven that the alleged invention claimed by the Asserted Claims of the '799 Patent was reduced to practice.
- 4. Whether or not Labcorp has proven that the alleged inventors of the alleged inventors claimed by the Asserted Claims of the '799 Patent were diligent in reducing to practice that invention.
- 5. Whether the Asserted Claims of the '799 Patent are directed to patent-ineligible subject matter.
 - 6. Whether the Asserted Claims of the '799 Patent are directed to an abstract idea.
- 7. Whether the Asserted Claims of the '799 Patent contain an inventive concept or merely well-understood, routine, and/or conventional activities, steps, or elements.
- 8. Whether the Asserted Claims of the '799 Patent are anticipated by the asserted prior art under 35 U.S.C. § 102.
- 9. Whether the prior art asserted against the Asserted Claims of the '799 Patent qualifies as prior art under pre-AIA 35 U.S.C. §§ 102(a), 102(b), 102(e), and/or 102(g).
- 10. Whether the prior art discloses each element of the Asserted Claims of the '799 Patent, explicitly or inherently.
- 11. Whether the Asserted Claims of the '799 Patent would have been obvious to one of ordinary skill in the art at the time of the alleged invention.

- 12. To the extent that there is any remaining dispute between the parties, the level of ordinary skill in the art at the time of the alleged invention of the Asserted Claims of the '799 Patent.
- 13. The scope and content of the prior art asserted against the Asserted Claims of the '799 Patent.
- 14. The differences, if any, between the claimed invention of the Asserted Claims of the '799 Patent and the asserted prior art.
- 15. Whether or not there are secondary considerations in support of the nonobviousness of the Asserted Claims of the '799 Patent.
- 16. Whether the Asserted Claims of the '799 Patent, read in light of the specification and the prosecution history, fail to inform, with reasonable certainty, a person of ordinary skill in the art about the scope of the alleged invention.
- 17. Whether the '799 Patent teaches those of ordinary skill in the art how to make and use the full scope of the claimed invention without undue experimentation.
- 18. Whether the '799 Patent describes the full scope of the claimed invention in sufficient detail so that they reasonably convey to one of ordinary skill in the art that the named inventors had possession of the claimed subject matter as of the filing date.

B. Invalidity of the '308 Patent

- 19. Whether or not Labcorp has proven the date to which it is entitled to claim priority for the Asserted Claims of the '308 Patent.
- 20. Whether or not Labcorp has proven the date on which the alleged invention claimed by the Asserted Claims of the '308 Patent was conceived.
- 21. Whether or not Labcorp has proven that the alleged invention claimed by the Asserted Claims of the '308 Patent was reduced to practice.

- 22. Whether or not Labcorp has proven that the alleged inventors of the alleged invention claimed by the Asserted Claims of the '308 Patent were diligent in reducing to practice that invention.
- 23. Whether the Asserted Claims of the '308 Patent are directed to patent-ineligible subject matter.
 - 24. Whether the Asserted Claims of the '308 Patent are directed to an abstract idea.
- 25. Whether the Asserted Claims of the '308 Patent contain an inventive concept or merely well-understood, routine, and/or conventional activities, steps, or elements.
- 26. Whether the Asserted Claims of the '308 Patent are anticipated by the asserted prior art under 35 U.S.C. § 102.
- 27. Whether the prior art asserted against the Asserted Claims of the '863 Patent qualifies as prior art under pre-AIA 35 U.S.C. §§ 102(a), 102(b), 102(e), and/or 102(g).
- 28. Whether the prior art discloses each element of the Asserted Claims of the '308 Patent, explicitly or inherently.
- 29. Whether the Asserted Claims of the '308 Patent would have been obvious to one of ordinary skill in the art at the time of the alleged invention.
- 30. To the extent that there is any remaining dispute between the parties, the level of ordinary skill in the art at the time of the alleged invention of the Asserted Claims of the '308 Patent.
- 31. The scope and content of the prior art asserted against the Asserted Claims of the '308 Patent.
- 32. The differences, if any, between the claimed invention of the Asserted Claims of the '308 Patent and the asserted prior art.

- 33. Whether or not there are secondary considerations in support of the nonobviousness of the Asserted Claims of the '308 Patent.
- 34. Whether the '308 Patent teaches those of ordinary skill in the art how to make and use the full scope of the claimed invention without undue experimentation.
- 35. Whether the '308 Patent describes the full scope of the claimed invention in sufficient detail so that they reasonably convey to one of ordinary skill in the art that the named inventors had possession of the claimed subject matter as of the filing date.

C. Invalidity of the '863 Patent

- 36. Whether or not Labcorp has proven the date to which it is entitled to claim priority for the Asserted Claims of the '863 Patent.
- 37. Whether or not Labcorp has proven the date on which the alleged invention claimed by the Asserted Claims of the '863 Patent was conceived.
- 38. Whether or not Labcorp has proven that the alleged invention claimed by the Asserted Claims of the '863 Patent was reduced to practice.
- 39. Whether or not Labcorp has proven that the alleged inventors of the alleged inventors claimed by the Asserted Claims of the '863 Patent were diligent in reducing to practice that invention.
- 40. Whether the Asserted Claims of the '863 Patent are directed to patent-ineligible subject matter.
 - 41. Whether the Asserted Claims of the '863 Patent are directed to an abstract idea.
- 42. Whether the Asserted Claims of the '863 Patent contain an inventive concept or merely well-understood, routine, and/or conventional activities, steps, or elements.
- 43. Whether the Asserted Claims of the '863 Patent are anticipated by the asserted prior art under 35 U.S.C. § 102.

- 44. Whether the prior art asserted against the Asserted Claims of the '308 Patent qualifies as prior art under 35 U.S.C. §§ 102(a), 102(b), 102(e), and/or 102(g).
- 45. Whether the prior art discloses each element of the Asserted Claims of the '863 Patent, explicitly or inherently.
- 46. Whether the Asserted Claims of the '863 Patent would have been obvious to one of ordinary skill in the art at the time of the alleged invention.
- 47. To the extent that there is any remaining dispute between the parties, the level of ordinary skill in the art at the time of the alleged invention of the Asserted Claims of the '863 Patent.
- 48. The scope and content of the prior art asserted against the Asserted Claims of the '863 Patent.
- 49. The differences, if any, between the claimed invention of the Asserted Claims of the '863 Patent and the asserted prior art.
- 50. Whether or not there are secondary considerations in support of the nonobviousness of the Asserted Claims of the '863 Patent.
- 51. Whether the '863 Patent teaches those of ordinary skill in the art how to make and use the full scope of the claimed invention without undue experimentation.
- 52. Whether the '863 Patent describes the full scope of the claimed invention in sufficient detail so that they reasonably convey to one of ordinary skill in the art that the named inventors had possession of the claimed subject matter as of the filing date.

II. REMEDIES TO LABCORP (IN THE EVENT LIABILITY IS FOUND)

53. In the event liability is found with respect to at least one of the Asserted Claims, whether or not Labcorp has proven an amount of damages in reasonable royalties, if any, to which

it is entitled, including underlying facts regarding the number of infringing acts and the appropriate reasonable royalty for such acts under 35 U.S.C. § 284.

- 54. In the event liability is found with respect to at least one of the Asserted Claims, whether or not Labcorp has proven that it is entitled to lost profits, including underlying facts regarding the number of infringing acts and the underlying facts regarding the factors articulated in *Panduit Corp. v. Stahlin Bros. Fibre Works*, 575 F. 2d 1152, 1156 (6th Cir. 1978), *i.e.*: (1) demand for the patented product; (2) absence of non-infringing alternatives; (3) manufacturing and marketing capability to exploit the demand; and (4) the amount of profit, if any, that Labcorp would have earned but for the alleged infringement.
- 55. In the event liability is found with respect to at least one of the Asserted Claims, whether Labcorp has proven that it is entitled to an award of pre-judgment and post-judgment interest for alleged infringement and if so, the amount.
- 56. In the event liability is found with respect to at least one of the Asserted Claims, whether Labcorp has established that the type of harm it allegedly has suffered, the alleged inadequacy of available remedies at law, the balance of hardship, and public interest warrant injunctive relief.
- 57. In the event liability is found, whether this is an exceptional case pursuant to 35 U.S.C. § 285.
- 58. In the event liability is found, whether attorney fees, expenses, and/or costs are due to Labcorp, and the amount.
- 59. In the event liability is found, whether costs should be limited under 35 U.S.C. § 288.

EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION AMERICA HOLDINGS,	ON OF)
Plaintiff,)) C.A. No. 21-669 (GBW)
V.)
NATERA, INC.,	<i>)</i>)
Defendan	t.)
LABORATORY CORPORATION AMERICA HOLDINGS,	ON OF)
Plaintiff,) C.A. No. 21-1635 (GBW)
V.)
NATERA, INC.,)
Defendan	t.)

EXHIBIT 4: PLAINTIFF LABORATORY CORPORATION OF AMERICA HOLDINGS' STATEMENT OF ISSUES OF LAW THAT REMAIN TO BE LITIGATED

Pursuant to Delaware Local Rule 16.3(c)(5), Plaintiff Laboratory Corporation of America Holdings ("Labcorp") hereby submit the following statement of issues of law that remain to be litigated.

This statement is based on the current status of the case and Court's rulings to date. Labcorp reserves the right to revise, amend, supplement, or modify the following statement based on any pretrial ruling by the Court and/or to address any additional issues, arguments, evidence, or other developments in the case, including edits to the draft pretrial order, any meet and confers or other negotiations between the parties, pending motions, and Defendant's identification of issues of law and fact to be litigated or any new issues Defendant may raise, or for other good cause. Labcorp does not assume the burden of proof with regard to any of the below-listed issues of law. Further details regarding these issues have been explained at length in Labcorp's pleadings and discovery responses, including in its contentions, interrogatory responses, expert reports, by experts at depositions and by fact witnesses at depositions, which Labcorp incorporates by reference. Should the Court determine that any issue identified in this list is more properly considered an issue of fact, it shall be so considered and Labcorp incorporates such issue into Labcorp's Statement of Issues of Facts That Remain to be Litigated (Ex. 2 to Proposed Final Pretrial Order). To the extent that Labcorp's Statement of Issues of Facts That Remain to be Litigated contains issues that the Court deems to be issues of law, those issues are incorporated herein by reference. The following statement of issues of law is not exhaustive and Labcorp reserves the right to prove any matters identified in the pleadings and discovery responses, including in its contentions, expert reports, by experts at depositions, and by fact witnesses at depositions. Labcorp intends to offer evidence as to the issues of fact and issues of law identified in this Pretrial Order. Labcorp further intends to offer evidence to rebut evidence offered by Defendant.

I. ISSUES ON WHICH LABCORP BEARS THE BURDEN OF PROOF

A. Infringement

Direct infringement occurs when the accused infringer "without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor." 35 U.S.C. § 271(a). Infringement, whether literal or under the doctrine of equivalents, is a question of fact. *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1275 (Fed. Cir. 2013); *Hilgraeve Corp. v. Symantec Corp.*, 265 F.3d 1336, 1341 (Fed. Cir. 2001).

To prove infringement, the patentee must show by a preponderance of the evidence, *i.e.*, that it is more likely than not, that an accused product embodies or practices all limitations of the claim. *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1341 n.15 (Fed. Cir. 2005); *Nuance Commc'ns Inc. v. Tellme Networks Inc.*, 707 F. Supp. 2d 472, 481 (D. Del. 2010). *Seal-Flex, Inc. v. Athletic Track and Court Const.*, 172 F.3d 836, 842 (Fed. Cir. 1999 "A patentee may prove infringement by any method of analysis that is probative of the fact of infringement, and circumstantial evidence may be sufficient." *Martek BioSciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1372 (Fed. Cir. 2009) (internal citations and quotations omitted); *see also Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 449 F.3d 1209, 1219 (Fed. Cir. 2006) ("A patentee may prove direct infringement or inducement of infringement by either direct or circumstantial evidence." (citation omitted)).

To prove direct infringement of a claim in a patent, a patentee must show that an accused product meets every limitation of the claim, either literally or under the doctrine of equivalents.

See Pfizer, Inc. v. Teva Pharms., USA, Inc., 429 F.3d 1364, 1376 (Fed. Cir. 2005). A two-step analysis is applied to determine infringement: first, the Court construes the asserted claims to determine their meaning and scope, and second the fact finder compares the accused product to the properly construed claims. See Nuance Commc'ns Inc. v. Tellme Networks Inc., 707 F. Supp. 2d 472, 480-481 (D. Del. 2010).

Literal infringement is shown where "the accused device contains or performs each limitation of the asserted claim." *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1313 (Fed. Cir. 2003). "The addition of unclaimed elements does not typically defeat infringement when a patent uses an open transitional phrase such as 'comprising." *Free Motion Fitness, Inc. v. Cybex Int'l, Inc.*, 423 F.3d 1343, 1347 (Fed. Cir. 2005); *see also Amstar Corp. v. Envirotech Corp.*, 730 F.2d 1476, 1482 (Fed. Cir. 1984) ("An accused device cannot escape infringement by merely adding features, if it otherwise has adopted the basic features of the patent.") (internal quotation marks omitted).

Infringement under the doctrine of equivalents may be found where an accused product performs substantially the same function in substantially the same way to obtain the same result. See Brilliant Instruments, Inc. v. GuideTech, LLC, 707 F.3d 1342 (Fed. Cir. 2013); Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 28 (1997). "A claim element is equivalently present in an accused device if only 'insubstantial differences' distinguish the missing claim element from the corresponding aspects of the accused device." Sage Prods Inc. v. Devon Indus., 126 F.3d 1420, 1423 (Fed. Cir. 1997). Whether a difference is "insubstantial" is evaluated from the perspective of the person of ordinary skill in the art and depends on the context of the patent, the prior art, and the particular circumstances of the case. See Brilliant Instruments, Inc., 707 F.3d at 1347-48. "Equivalence... does not require complete identity for every purpose and

in every respect." *Warner-Jenkinson Co.*, 520 U.S. at 24-25 (internal quotation marks omitted). Known interchangeability of a claim element and the proposed equivalent is a factor that can support a finding of infringement under the doctrine of equivalents. *See id.* at 36 ("The known interchangeability of substitutes for an element of a patent is one of the express objective factors ... bearing upon whether the accused device is substantially the same as the patented invention.").

"Infringement, literal or by equivalence, is determined by comparing an accused product not with a preferred embodiment described in the specification, or with a commercialized embodiment of the patentee, but with the properly and previously construed claims in suit." *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985). "[I]t is error for a court to compare in its infringement analysis the accused product or process with the patentee's commercial embodiment or other version of the product or process; the only proper comparison is with the claims of the patent." *Zenith Labs. Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423 (Fed. Cir. 1994); *see also ACCO Brands, Inc. v. Micro Sec. Devices, Inc.*, 346 F.3d 1075, 1081-82 (Fed. Cir. 2003) ("The language of the claim, not the patent owner's commercial product, is the measure of infringement.").

Literal infringement does not require intent. See Warner-Jenkinson Co., 520 U.S. at 35 ("Application of the doctrine of equivalents, therefore, is akin to determining literal infringement, and neither requires proof of intent."); Intel Corp. v. United States Int'l Trade Comm'n, 946 F.2d 821, 832 (Fed. Cir. 1991) ("there is no intent element to direct infringement.").

B. Invalidity

A defendant challenging the validity of a patent bears the burden of proving invalidity by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd.*, 564 U.S. 91, 95 (2011). "A patent shall be presumed valid." 35 U.S.C. § 282. A defendant that challenges patent validity "must

overcome that presumption to prevail on an invalidity defense," *Microsoft Corp.*, 564 U.S. at 100 (2011), and a court may conclude that a patent is valid "*solely* on the failure of the patent challenger's evidence to convincingly establish the contrary." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1570 (Fed. Cir. 1986) (emphasis in original).

1. Priority

When a party seeks the benefit of an earlier-filed United States patent application, the earlier application must meet the requirements of 35 U.S.C. § 120 and 35 U.S.C. § 112 ¶ 1, which means the earlier application must contain a written description of the subject matter and must meet the enablement requirement. *See Hyatt v. Boone*, 146 F.3d 1348, 1352 (Fed. Cir. 1998). 35 U.S.C. § 120 allows a later-filed patent application to claim the benefit of an earlier filing date in the United States if "the claims of the later-filed application [are] supported by the written description in the parent 'in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." *EnOcean GmbH v. Face Intern. Corp.*, 742 F.3d 955, 960 (Fed. Cir. 2014).

If the party challenging validity comes forward with clear and convincing evidence of invalidating prior art that puts at issue the priority date of any claim of a patent, the burden shifts to the patentee "to come forward with evidence to prove entitlement to claim priority to a filing date that predates the filing date of the patent." *Fairchild Semiconductor Corp. v. Power Integrations*, 100 F. Supp. 3d 357, 368 (D. Del. 2015) (citing *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305-06 (Fed. Cir. 2008)). To meet this burden, the patentee must demonstrate that "the disclosure of the earlier application provides support for the claims of the later application, as required by 35 U.S.C. § 112." *PowerOasis*, 522 F.3d at 1306 (citing *In re Chu*, 66 F.3d 292, 297 (Fed. Cir. 1995)).

A "prior application need not contain precisely the same words as are found in the asserted claims," but "the prior application must indicate to a person skilled in the art that the inventor was 'in possession' of the invention as later claimed." *Id.* (citations omitted). "[I]t is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention." *LizardTech Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005); *see also Eiselstein v. Frank*, 52 F.3d 1035, 1038 (Fed. Cir. 1995) ("[T]he prior application need not describe the claimed subject matter in exactly the same terms as used in the claims; it must simply indicate to persons skilled in the art that as of the earlier date the applicant had invented what is now claimed.").

A prior inventor's testimony concerning conception, reduction to practice, and diligence must be reasonably corroborated by evidence, and such corroborating evidence is considered "as a whole" under a "rule of reason." *Price v. Symsek*, 988 F.2d 1195-96 (Fed. Cir. 1993); *see also Cooper v. Goldfarb*, 154 F.3d 1321, 1331 (Fed. Cir. 1998) ("[t]he law does not impose an impossible standard of 'independence' on corroborative evidence by requiring that every point of a reduction to practice be corroborated by evidence having a source totally independent of the inventor; indeed, such a standard is the antithesis of the rule of reason.") (citation omitted).

2. Personal of Ordinary Skill in the Art

The person of ordinary skill in the art is an objective legal construct presumed to think along conventional lines without undertaking to innovate, whether by systematic research or by extraordinary insights. Inventors, as a class, according to concepts underlying the Constitution and the statutes that have created the patent system, possess something—call it what you will—which sets them apart from workers of ordinary skill, and one should not go about determining obviousness under 35 U.S.C. § 103 by inquiring into what patentees ... would have known or

would likely have done, faced with the revelations of references. *See Life Technologies, Inc. v. Clontech Laboratories, Inc.*, 224 F.3d 1320 (Fed. Cir. 2000).

Factors that may be considered in determining the ordinary level of skill in the art include:

1) the types of problems encountered in the art; 2) the prior art solutions to those problems; 3) the rapidity with which innovations are made; 4) the sophistication of the technology; and 5) the educational level of active workers in the field. "Not all such factors may be present in every case, and one or more of them may predominate." *Ruiz v. A.B. Chance Co.*, 234 F.3d 654 (Fed. Cir. 2000).

The foundation for both the obviousness and claim construction determinations is "the level of ordinary skill in the pertinent art." *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). A person or ordinary skill is also a person of ordinary creativity, not an automaton. *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). Applications of the standard have confirmed that this standard envisions persons of relative sophistication within the field of the invention. *Helifix Ltd. v. Block-Lok, Ltd.*, 26 F. Supp. 2d 294 (D. Mass. 1998), judgment vacated on other grounds, 208 F.3d 1339 (Fed. Cir. 2000).

C. Remedies

1. Patent Damages

35 U.S.C. § 284 provides "[u]pon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court." "[T]he amount of a prevailing party's damages is a finding of fact on which the plaintiff bears the burden of proof by a preponderance of the evidence." *Smithkline Diagnostics, Inc. v. Helena Labs. Corp.*, 926 F.2d 1161, 1164 (Fed. Cir. 1991). The patent statute

"imposes no limitation on the types of harm resulting from infringement that the statute will redress. The section's broad language awards damages for any injury as long as it resulted from the infringement." *King Instruments Corp. v. Perego*, 65 F.3d 941, 947 (Fed. Cir. 1995).

A patentee need not prove its damages with absolute certainty. See W.R. Grace & Co.-Conn. v. Intercat, Inc., 60 F. Supp. 2d 316, 321 (D. Del. 1999) (citing Lam, Inc. v. Johns-Manville Corp., 718 F.2d 1056, 1065 (Fed. Cir. 1983)). "[I]t will be enough if the evidence show [sic] the extent of the damages as a matter of just and reasonable inference, although the result be only approximate." Story Parchment Co. v. Patterson Paper Co., 282 U.S. 555, 563 (1931). "Any doubt about the correctness [of damages] is resolved against the infringer." State Indus., Inc. v. Mor-Flo Indus., Inc., 883 F.2d 1573, 1577 (Fed. Cir. 1989).

(i) Lost Profits

"A patentee may seek to recover actual damages, usually, the amount of profits actually lost" *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 926 F.2d 1161, 1164 (Fed. Cir. 1991) (citations omitted). "[T]he amount of a prevailing party's damages is a finding of fact on which the plaintiff bears the burden of proof by a preponderance of the evidence." *Id.* "The patent owner bears the burden to present evidence sufficient to show a reasonable probability that it would have made the asserted profits absent infringement." *King Instruments*, 65 F.3d at 952.

"[T]he statutory measure of 'damages' is 'the difference between [the patent owner's] pecuniary condition after the infringement, and what his condition would have been if the infringement had not occurred." *Grain Processing Corp. v. American Maize-Products Co.*, 185 F.3d 1341, 1350 (Fed. Cir. 1999). To prove lost profits, a patentee must reconstruct the market to show "likely outcomes with infringement factored out of the economic picture." *Id*.

To recover lost profits based on lost sales, the patent owner has an initial burden to show "but for" the infringement the patent owner would have made the infringer's sales. *Crystal Semiconductor Corp. v. Tritech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1353 (Fed. Cir. 2001). "But the patent holder does not need to negate all possibilities that a purchaser might have bought a different product or might have foregone the purchase altogether." *State Indus., Inc. v. Mor-Flo Indus., Inc.*, 883 F.2d 1573, 1577 (Fed. Cir. 1989) (quotation and citation omitted). Once the patent owner has met its initial burden, "[t]he burden then shifts to the infringer to show that the ['but for' claim] is unreasonable for some or all of the lost sales." *Rite-Hite Corp. v. Kelley Co., Inc.*, 56 F.3d 1538, 1545 (Fed. Cir. 1995). In a two-supplier market, it may be inferred that the patentee would have made the infringer's sales or charged higher prices but for the competition. *See State Indus.*, 883 F.2d at 1573.

One recognized method by which a plaintiff may prove the amount of its lost profits is based on the *Panduit* factors: (1) demand for the patented product; (2) absence of acceptable non-infringing substitute products; (3) manufacturing and marketing capability to meet the demand; and (4) the amount of the profit that would have been earned. *See Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978); *Versata Software, Inc. v. SAP Am., Inc.*, 717 F.3d 1255, 1265 (Fed. Cir. 2013). "A showing under Panduit permits a court to reasonably infer that the lost profits claimed were in fact caused by the infringing sales, thus establishing a patentee's prima facie case with respect to 'but for' causation." *Rite-Hite*, 56 F.3d at 1545.

With regard to the first factor:

All that the first factor states, and thus requires, is "demand for the patented product." Panduit, 575 F.2d at 1156. This factor does not require any allocation of consumer demand among the various limitations recited in a patent claim. Instead, the first Panduit factor simply asks whether demand existed for the "patented product," i.e., a product that is "covered by the patent in suit" or that "directly

competes with the infringing device."

DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 567 F.3d 1314, 1330 (Fed. Cir. 2009). Commercial success is compelling evidence of demand. See Gyromat Corp. v. Champion Spark Plug, Co., 735 F.2d 549, 552 (Fed. Cir. 1984).

With regard to the second factor:

When an alleged alternative is not on the market during the accounting period, a trial court may reasonably infer that it was not available as a noninfringing substitute at that time ... The accused infringer then has the burden to overcome this inference by showing that the substitute was available during the accounting period ... Mere speculation or conclusory assertions will not suffice to overcome the inference. After all, the infringer chose to produce the infringing, rather than noninfringing, product. Thus, the trial court must proceed with caution in assessing proof of the availability of substitutes not actually sold during the period of infringement. Acceptable substitutes that the infringer proves were available during the accounting period can preclude or limit lost profits; substitutes only theoretically possible will not.

Grain Processing, 185 F.3d at 1353. "While there may be competing devices available in the marketplace, the 'mere existence of a competing device does not make that device an acceptable substitute." Kalman v. Berlyn Corp., 914 F.2d 1473, 1484 (Fed. Cir. 1990) (citation omitted). "It is clear that '[a] product lacking the advantages of [the] patented [device] can hardly be termed a substitute 'acceptable' to the customer who wants those advantages." Id. (citation omitted).

The patent owner may prove the third *Panduit* factor—capacity—by showing that it had the ability to meet the demand for the quantity of sales that it claims to have lost. *See Fonar Corp.* v. Gen. Elec. Co., 107 F.3d 1543, 1553 (Fed. Cir. 1997).

The patent owner may prove the fourth Panduit factor—the amount of profits it lost—by reasonably quantifying the incremental profits it would have made from the sales it lost. *See Paper Converting Machine Co. v. Magna-Graphics Corp.*, 745 F.2d 11, 22 (Fed. Cir. 1984). Classic computation of lost sales to infringing products applies the patent owner's profit margin to the

revenue the patent owner would have generated based on the number of infringing units the infringer sold. *See King Instruments Corp.*, 65 F.3d at 953. "[F]ixed costs—those costs which do not vary with increases in production, such as management salaries, property taxes, and insurance—are excluded when determining profits." *Paper Converting*, 745 F.2d at 22 (citations omitted).

(ii) Reasonable Royalty

A plaintiff is entitled to damages equivalent to a reasonable royalty, or the amount that the defendant would have paid for a license to the asserted patents if the parties had negotiated a license at the time of first alleged infringement. *See LaserDynamics, Inc. v. Quanta Computer,* Inc., 694 F.3d 51, 60 (Fed. Cir. 2012). "The district court must award damages in an amount no less than a reasonable royalty." *Dow Chem. Co. v. Mee Indust., Inc.*, 341 F.3d 1370, 1381-82 (Fed. Cir. 2003) (citing 35 U.S.C. § 284).

The reasonable royalty may be based on a determination of "the royalty upon which the parties would have agreed had they successfully negotiated an agreement just before infringement began," i.e., the "hypothetical negotiation." *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009); *see also Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1357 (Fed. Cir. 2012). If the record does not fully support either party's royalty estimate, then the fact finder must determine what constitutes a reasonable royalty from the record evidence. *See Apple, Inc. v. Motorola, Inc.*, 757 F.3d 1286, 1328 (Fed. Cir. 2014).

To determine a reasonable royalty, courts may apply the fifteen factors established in Georgia-Pacific v. U.S. Plywood Corp.:

1. Any royalties received by the licensor for the licensing of the Asserted Patents, proving or tending to prove an established royalty.

- 2. The rates paid by Defendant to license other patents comparable to the Asserted Patents.
- The nature and scope of the license, as exclusive or non-exclusive, or as restricted or non-restricted in terms of its territory or with respect to whom the manufactured product may be sold.
- 4. The licensor's established policy and marketing program to maintain its right to exclude others from using the patented invention by not licensing others to use the invention, or by granting licenses under special conditions designed to preserve that exclusivity.
- 5. The commercial relationship between the licensor and the licensee, such as whether or not they are competitors in the same territory in the same line of business.
- 6. The effect of selling the patented product in promoting other sales of the licensee; the existing value of the invention to the licensor as a generator of sales of its nonpatented items; and the extent of such collateral sales.
- 7. The duration of the Asserted Patents and the term of the license.
- 8. The established profitability of the product made under the Asserted Patents; its commercial success; and its popularity.
- 9. The utility and advantages of the patented invention over the old modes or devices, if any, that had been used for achieving similar results.
- 10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by or for the licensor; and the benefits to those who have used the invention.

- 11. The extent to which Defendant has made use of the invention; and any evidence that shows the value of that use.
- 12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.
- 13. The portion of the profit that arises from the patented invention itself as opposed to profit arising from unpatented features, such as the manufacturing process, business risks, or significant features or improvements added by the accused infringer.
- 14. The opinion testimony of qualified experts.
- 15. The amount that a licensor and a licensee if both sides had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee—who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention—would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a patentee who was willing to grant a license.
- 16. Any other economic factor that a normally prudent business person would, under similar circumstances, take into consideration in negotiating the hypothetical license.

See Georgia-Pacific Corp. v. United States Plywood Corp., 318 F. Supp. 1116 (S.D.N.Y. 1970), mod. and aff'd, 446 F.2d 295 (2d Cir. 1971).

"In determining a reasonable royalty, parties frequently rely on comparable license agreements." *Bio-Rad Lab'ys, Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1372 (Fed. Cir. 2020) (citing *Georgia–Pacific Corp.*, 318 F. Supp. at 1120). "Assessing the comparability of licenses requires a consideration of whether the license at issue involves comparable technology, is

economically comparable, and arises under comparable circumstances as the hypothetical negotiation." *Id.* at 1372-73. "Such a model begins with rates from comparable licenses and then 'account[s] for differences in the technologies and economic circumstances of the contracting parties." *Commonwealth Sci. & Indus. Research Organisation v. Cisco Sys., Inc.*, 809 F.3d 1295, 1303 (Fed. Cir. 2015), cert. denied, 136S. Ct. 2530, 195 L. Ed. 2d 859 (2016). "Wherethe licenses employed are sufficiently comparable, this method is typically reliable because the parties are constrained by the market's actual valuation of the patent." *Id.* When the comparable license approach is used, apportionment to the smallest salable patent-practicing unit is not required. *See id.*

When a patentee seeks damages on unpatented components sold with a patented apparatus, courts have applied a formulation known as the 'entire market value rule' to determine whether such components should be included in the damage computation, whether for reasonable royalty purposes [] or for lost profits purposes[]. ... The entire market value rule has typically been applied to include in the compensation base unpatented components of a device when the unpatented and patented components are physically part of the same machine. See, e.g., Western Elec. Co. v. Stewart-Warner Corp., 631 F.2d 333, 208 USPQ 183 (4th Cir. 1980), cert. denied, 450 U.S. 971, 101 S.Ct. 1492, 67 L.Ed.2d 622 (1981). The rule has been extended to allow inclusion of physically separate unpatented components normally sold with the patented components. See, e.g., Paper Converting, 745 F.2d at 23, 223 USPQ at 599. However, in such cases, the unpatented and patented components together were considered to be components of a single assembly or parts of a complete machine, or they together constituted a functional unit. See, e.g., Velo-Bind, Inc. v. Minnesota Mining & Mfg. Co., 647 F.2d 965, 211 USPQ 926 (9th Cir.), cert. denied, 454 U.S. 1093, 102 S.Ct. 658, 70 L.Ed.2d 631 (1981).

Rite-Hite, 56 F.3d at 154-50. The combination of the royalty base and royalty rate must reflect the value attributable to the infringing features of the product. *See Ericsson, Inc. v. D-Link Sys. Inc.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014).

When a patent claims a novel combination of conventional elements, "the question is how much new value is created by the novel combination, beyond the value conferred by the

conventional elements alone." *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1339 (Fed. Cir. 2015).

(iii) Attorneys' Fees

"The court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. "An "exceptional' case is "one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1756 (2014). "District courts may determine whether a case is "exceptional" in the case-by-case exercise of their discretion, considering the totality of the circumstances." *Id.* Relevant factors for consideration include "frivolousness, motivation, objective unreasonableness (both in the factual and legal components of the case) and the need in particular circumstances to advance considerations of compensation and deterrence." *Id.* at 1756 n.6 (quotation and citation omitted).

(iv) Prejudgment and Post-Judgment Interest

The patent statute authorizes awards of prejudgment interest. 35 U.S.C. § 284. The Supreme Court has held that "prejudgment interest should ordinarily be awarded where necessary to afford the plaintiff full compensation for the infringement." *Gen. Motors Corp. v. Devex Corp.*, 461 U.S. 648, 654 (1983). "An award of prejudgment interest serves to make the patentee whole because the patentee also lost the use of its money due to infringement." *Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc.*, 246 F.3d 1336, 1361 (Fed. Cir. 2001).

"The rate of prejudgment interest and whether it should be compounded or uncompounded are matters left largely to the discretion of the district court.... In exercising that discretion, however, the district court must be guided by the purpose of prejudgment interest, which is 'to

ensure that the patent owner is placed in as good a position as he would have been had the infringer entered into a reasonable royalty agreement." *Bio-Rad Labs, Inc. v. Nicolet Instrument Corp.*, 807 F.2d 964, 969 (Fed. Cir. 1986) (citations omitted). "The prime rate is by far the most common practice in the District of Delaware." *ArcherDX, LLC v. Qiagen Sciences, LLC*, No. 18-1019 (MN), 2022 WL 4597877, at *18 (D. Del. Sep. 30, 2022) (collecting cases).

Post-judgment interest is mandated in civil cases at "a rate equal to the weekly average 1-year constant maturity Treasury yield [] for the calendar week preceding the date of the judgment." 28 U.S.C. § 1961. Post-judgment interest on the total money award is computed daily and compounded annually. *See id*.

(v) Costs

"Federal Rule of Civil Procedure 54(d) gives courts the discretion to award costs to prevailing parties." *Taniguchi v. Kan Pac. Saipan, Ltd.*, 132 S. Ct. 1997, 2001 (2012). "Unless a federal statute, these rules, or a court order provides otherwise, costs—other than attorney's fees—should be allowed to the prevailing party." Fed. R. Civ. P. 54(d)(l).

2. Permanent Injunction

Upon the request of a patentee, the Court may permanently enjoin the infringer, during the life of the patent, from continuing with the activity found to have infringed the patent. *See eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

To grant a permanent injunction, a patent holder must demonstrate (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the patentee and infringer, a remedy in equity is warranted; and (4) the public interest would not be disserved by a permanent injunction. *See eBay Inc.*, 547 U.S. at 391.

II. RESPONSE TO DEFENDANT'S STATEMENT OF ISSUES OF LAW ON WHICH DEFENDANTS BEAR THE BURDEN OF PROOF

A. Validity Of The Patents-In-Suit

1. Person Of Ordinary Skill In The Art

Labcorp incorporates its statement in Part I.B.2. See supra.

2. Presumption of Validity

A defendant challenging the validity of a patent bears the burden of proving invalidity by clear and convincing evidence. *Microsoft Corp. v. i4i Ltd.*, 564 U.S. 91, 95 (2011). "A patent shall be presumed valid." 35 U.S.C. § 282. A defendant that challenges patent validity "must overcome that presumption to prevail on an invalidity defense," *Microsoft Corp.*, 564 U.S. at 100 (2011), and a court may conclude that a patent is valid "solely on the failure of the patent challenger's evidence to convincingly establish the contrary." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1570 (Fed. Cir. 1986) (emphasis in original).

3. Priority Date and Prior Art Status

Labcorp incorporates its statement in Part I.B.1. See supra.

Whether an alleged reference is prior art, presents a question of law based on underlying factual inquires. *TypeRight Keyboard Corp. v. Microsoft Corp.*, 374 F.3d 1151, 1157 (Fed. Cir. 2004). The challenger to a patent's validity, as part of proving its case of invalidity, bears the burden of proving, by clear and convincing evidence, that an asserted invalidating reference qualifies as prior art. *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996)

As a consequence of the statutory presumption of validity, a party that asserts the invalidity of any claim of a patent has the initial burden of production and always has the burden of persuasion of proving invalidity. 35 U.S.C.A. § 282. The accused infringer, rather than the patentee, bears the burden of showing that alleged prior art was not considered by the Patent Office.

Richdel, Inc. v. Sunspool Corp., 714 F.2d 1573, 1579, 219 U.S.P.Q. 8 (Fed. Cir. 1983). "Gennum, having the ultimate burden of proving its defense of invalidity based on anticipating prior art, then has the burden of going forward with evidence that there is such anticipating prior art." Tech. Licensing Corp. v. Videotek, Inc., 545 F.3d 1316, 1327 (Fed. Cir. 2008); see also Dynamic Drinkware, LLC v. National Graphics, Inc., 800 F.3d 1375, 1379. (Fed. Cir. 2015)

4. Prior art Before a Patent Examiner

Under 35 U.S.C. § 282(a), a patent and each of the claims therein are presumed to be valid. See Microsoft Corp. v. I4I Ltd. Partnership, 564 U.S. 91 (2011). The presumption of validity applies to all persons seeking to challenge the validity of the patent even if those persons had no involvement or right to be heard during the prosecution of the patent before the Patent Office. See Radio Corporation of America v. Radio Engineering Laboratories, 293 U.S. 1 (1934). The presumption of validity applies to all aspects of patent validity and exists at all stages of litigation. Canon Computer Systems, Inc. v. Nu-Kote Intern., Inc., 134 F.3d 1085, 1088 (Fed. Cir. 1998) ("a patent is presumed valid, and this presumption exists at every stage of the litigation"—applying presumption to affirm preliminary injunction); see also Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1375 (Fed. Cir. 1986); Panduit Corp. v. Dennison Mfg. Co., 810 F.2d 1561, 1570 (Fed. Cir. 1987). An accused infringer may not offer testimony calling into question the competence of PTO examiners absent "evidence that there actually were defects in the particular application process at issue in this case." Bausch & Lomb, Inc. v. Alcon Laboratories, Inc., 79 F. Supp. 2d 252, 255–56 (W.D. N.Y. 2000).

5. Patent Eligibility¹

The question of "whether a claim is directed to statutory subject matter is a question of law." *Arrhythmia Research Technology, Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1055, 22 U.S.P.Q.2d 1033 (Fed. Cir. 1992). Claims are patent eligible unless they are both (1) directed towards ineligible subject matter such as an abstract idea; and (2) fail to add an "inventive concept" to the ineligible subject matter to which they are directed. *See Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 217-18 (2014).

"The concern underlying the exceptions to § 101 is not tangibility, but preemption." *McRO, Inc. v. Bandai Namco Games America Inc.*, 837 F.3d 1299, 1314 (Fed. Cir. 2016). The Federal Circuit has "routinely held software claims patent eligible under *Alice* step one when they are directed to improvements to the functionality of a computer or network platform itself." *Uniloc USA, Inc. v. LG Electronics USA, Inc.*, 957 F.3d 1303, 1307 (Fed. Cir. 2020). In *Enfish*, the Federal Circuit was emphatic that software inventions can be patent eligible:

Nor do we think that claims directed to software, as opposed to hardware, are inherently abstract and therefore only properly analyzed at the second step of the *Alice* analysis. Software can make non-abstract improvements to computer technology just as hardware improvements can, and sometimes the improvements can be accomplished through either route.

Enfish, LLC v. Microsoft Corp., 822 F.3d 1327, 1336 (Fed. Cir. 2016).

In *McRo*, the claims found eligible were directed to an improved software approach to computer animation. *McRo*, 837 F.3d at 1314. The Federal Circuit explained that the improvement was in the computerized rules set forth in the claims, not the mere computerization

¹ Labcorp objects to Defendant's statement of the patentable subject matter issue as an issue that remains to be litigated at the jury trial. This issue has already been resolved by the Court, finding the claims were not directed to an abstract idea under Alice step one. Dkt. No. 28.

of the animation process. Id. ("It is the incorporation of the claimed rules, not the use of the computer, that improved the existing technological process by allowing the automation of further tasks.") (alterations omitted). In Enfish, the claims found eligible were directed to a self-referential table that stores computer data. Enfish, 822 F.3d at 1339. The claimed software table was innovative relative to prior art tables in very specific ways that were claimed. *Id.* at 1138 ("For example, step three of the algorithm described above explains that the table stores information related to each column in rows of that very same table, such that new columns can be added by creating new rows in the table."). The Federal Circuit explained that, given the particulars of the table, "the claims are directed to a specific implementation of a solution to a problem in the software arts." *Id.* at 1339. In *Data Engine*, the claims found eligible were directed to a specific method for navigating through three-dimensional electronic spreadsheets. Data Engine Techs. LLC v. Google LLC, 906 F.3d 999, 1008 (Fed. Cir. 2018). The Federal Circuit recognized that the claim "provides a specific solution to then-existing technological problems in computers and prior art electronic spreadsheets." Id. The Federal Circuit explained that the claims specifically described the steps that would improve the spreadsheet performance. *Id.* ("The claim recites specific steps detailing the method of navigating through spreadsheet pages within a threedimensional spreadsheet environment using notebook tabs.").

6. Anticipation

A patent claim is invalid as anticipated if "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." 35 U.S.C. § 102(a). A defendant must demonstrate by clear and convincing evidence that "each and every" element and limitation of the claim was previously described in a single prior art reference, either expressly or inherently. *See Allergan*,

Inc. v. Apotex Inc., 754 F.3d 952, 958 (Fed. Cir. 2014). See also Merck & Co., Inc. v. Teva Pharmaceuticals USA, Inc., 347 F.3d 1367, 1372 (Fed. Cir. 2003) ("An 'anticipating' reference must describe all of the elements and limitations of the claim in a single reference, and enable one of skill in the field of the invention to make and use the claimed invention."); Kyocera Wireless Corp. v. International Trade Com'n, 545 F.3d 1340, 1351 (Fed. Cir. 2008); Dewey & Almy Chem. Co v. Mimex Co, 124 F.2d 986, 989 (2d Cir. 1942). Showing that a "prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention" is not enough for anticipation. Net MoneyIN, Inc. v. VeriSign, Inc., 545 F.3d 1359, 1371 (Fed. Cir. 2008).

In order to constitute an invalidating prior-art reference, a printed publication "must sufficiently describe the claimed invention to have placed the public in possession of it." *In re Donohue*, 766 F.2d 531,533 (Fed. Cir. 1985). In particular, the proper test for whether the public is in possession is "whether one skilled in the art to which the invention pertains could take the description of the invention in the printed publication and combine it with his own knowledge of the particular art and from this combination be put in possession of the invention on which a patent is sought. In particular, one must be able to make the claimed invention without undue experimentation." *In re Elsner*, 381 F.3d 1125, 1128 (Fed. Cir. 2004). Showing that a "prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention" is not enough for anticipation. *Net Money IN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008).

Further, the anticipating reference must be enabling. Sanofi-Synthelabo. 550 F.3d at 1082. "[I]nvalidity by anticipation requires that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." Advanced Display Sys. Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000). In trying to show anticipation, "one skilled in the art cannot supply missing elements through his or her knowledge." Forest Labs., Inc. v. Ivax Pharms., Inc., 438 F. Supp. 2d 479, 485 (D. Del. 2006), aff'd, 501 F.3d 1263 (Fed. Cir. 2007). For anticipation, "[t]here must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed. Cir. 1991), overruled in part for other reasons by Abbott Labs. v. Sandoz, Inc., 566 F.3d 1282 (Fed. 39 Cir. 2009). A prior-art reference that does not disclose a limitation may inherently anticipate the limitation when the reference must "include the unstated limitation." Transclean Corp. v. Bridgewood Servs., Inc., 290 F.3d 1364, 1373 (Fed. Cir. 2002). For a reference to be inherently anticipatory, the missing element *must necessarily be present*, not merely "probably or possibly present." Trintec Indus. Inc. v. Top-U.S.A. Corp., 295 F.3d 1292 (Fed. Cir. 2002) (citing In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999). Inherent anticipation cannot "be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." Cont'l Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1268-69 (Fed. Cir. 1991) (internal quotation marks omitted).

Public policy prohibits the use of non-public works as prior art to defeat a patent claim. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 1550, (Fed. Cir. 1983) (holding that secret use is not prior art under 35 U.S.C.A. § 102(a),(b)—"There is no reason or statutory basis, however, on which Budd's and Cropper's secret commercialization of a process, if established, could be held a bar to the grant of a patent to Gore on that process. ... The district court therefore erred as a matter of law in applying the statute and in its determination that Budd's secret use of the Cropper machine and sale of tape rendered all process claims of the '566 patent invalid under § 102(b).") *International Glass Co. v. U. S.*, 408 F.2d 395, 402 (1969) (prior invention of a process did not invalidate a patent on the same process under § 102(g) because the prior inventors did nothing to make the invention known to the public).

7. Non-Obviousness

Obviousness is a matter of law and depends on the following factual inquiries: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the relevant art; and (4) any objective indicia of nonobviousness. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). 35 U.S.C. § 103 provides the following:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 103. A party seeking to invalidate a patent based on obviousness must demonstrate "by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007); *see also In re Cyclobenzaprine Hydrochloride Extended-Release*

Capsule Patent Litig., 676 F.3d 1063, 1068-69 (Fed. Cir. 2012). In analyzing obviousness, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." KSR Inter. Co., 550 U.S. at 418.

Both the suggestion and the reasonable expectation of success "must be founded in the prior art, not in the applicant's disclosure." *Noelle v. Lederman*, 355 F.3d 1343, 1352 (Fed. Cir. 2004). "Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination," *Unigene Labs., Inc. v. Apotex, Inc.*, 655 F.3d 1352, 1360 (Fed. Cir. 2011), and "[a] solution is not obvious simply because it was obvious to conduct experiments to try to solve the problem." *Vanda Pharms. Inc. v. Roxane Labs., Inc.*, 203 F. Supp. 3d 412, 427 (D. Del. 2016), *aff'd*, 887 F.3d 1117 (Fed. Cir. 2018); *see also Abbott Labs.*, 334 F.3d at 1357.

To avoid "distortion caused by hindsight bias," there must be "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR Inter. Co.*, 550 U.S. at 418, 421; *see also id.* at 421 ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning."); *Novartis Pharms. Corp. v. Par Pharm.*, *Inc.*, 48 F. Supp. 3d 733, 752 (D. Del. 2014) (a party seeking to invalidate a patent claim "must show that a PHOSITA would be motivated to combine the claimed combinations with a reasonable expectation of success.").

8. Secondary Considerations of Non-Obviousness

An obviousness determination requires consideration of the objective indicia of nonobviousness (or "secondary considerations") such as licensing, praise, unexpected results, commercial success, copying, skepticism, failure of others, and long-felt but unresolved need.

KSR, 550 U.S. at 406; Apple Inc. v. Samsung Elecs. Co., Ltd., 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc) ("Objective indicia of nonobviousness must be considered in every case where present."). There must also be a nexus between the objective indicia and the claimed invention. Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392 (Fed. Cir. 1988).

9. Written Description

Pursuant to 35 U.S.C. § 112(a), "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same." To overcome the presumed validity of a patent, a defendant challenging whether a patent meets the written description requirement of 35 U.S.C. § 112(a) "must show that the claims lack a written description by clear and convincing evidence." *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1351 (Fed. Cir. 2011).

Pursuant to Section 112(a) of the Patent Act, "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same." 35 U.S.C. § 112(a). To overcome the presumed validity of a patent, a defendant challenging whether a patent meets the written description requirement of 35 U.S.C. § 112(a) "must show that the claims lack a written description by clear and convincing evidence." *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336, 1351 (Fed. Cir. 2011). The inventor is not required to satisfy this requirement by "any particular form of disclosure." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (*en banc*). The level of disclosure that is required is subject to a variety of considerations "such as the existing knowledge in a particular field, the extent and content of the prior art, the maturity of the science or technology, the

predictability of the aspect at issue, and other considerations appropriate to the subject matter." *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005).

10. Definiteness²

Section 112(b) of the Patent Act requires claims to "particularly point[] out and distinctly claim[] the subject matter which the inventor or a joint inventor regards as the invention." 35 U.S.C. § 112(b). A determination of claim definiteness is a question of law. *Personalized Media Commc'ns*, *LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 705 (Fed. Cir. 1998). A defendant challenging a patent's validity has the burden to prove the indefiniteness requirement by clear and convincing evidence. *BSAF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017).

Indefiniteness of a claim is evaluated from the perspective of a person skilled in the relevant art. See Nautilus, Inc. v. BioSig Instruments, Inc., 572 U.S. 898, 908 (2014). Moreover, the claim is evaluated in light of the patent's specification and prosecution history, and measured as of the time of the patent application. Id. Thus, reference to publications or patents in the specification are part of that disclosure, and are included in the inquiry of whether a claim, read in light of the specification and prosecution history, informs "with reasonable certainty" those skilled in the art about the scope of the invention, even if such references are not incorporated by reference. Atmel Corp. v. Information Storage Devices, Inc., 198 F.3d 1374 1383 (Fed. Cir. 1999) (stating that "the district court erred by failing to consider the knowledge of one skilled in the art that indicated, based on unrefuted testimony, that the specification disclosed sufficient structure corresponding

² Labcorp objects to Defendant's statement of the definiteness issue as a contested fact that remains to be litigated at the jury trial. "A determination of claim definiteness is a question of law." *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 705 (Fed. Cir. 1998). *See also Atmel Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374, 1378 (Fed. Cir. 1999) ("Indefiniteness, therefore, like claim construction, is a question of law that we review de novo."); *Nature Simulation Sys. Inc. v. Autodesk, Inc.*, 50 F.4th 1358, 1360 (Fed. Cir. 2022).

to the high-voltage means limitation" by citing, but not describing, a technical article); see also Eli Lilly & Co. v. Teva Parenteral Medicines Inc., 845 F.3d 1357, 1370-72 (Fed. Cir. 2017) (holding the claim term "vitamin B12" as not indefinite when a person of ordinary skill in the art would understand the claim term in the context of the claim language, specification, and prosecution history).

"The claims as granted are accompanied by a presumption of validity based on compliance with, inter alia, § 112 ¶ 2." S3 Inc. v. Nvidia Corp., 259 F.3d 1364, 1367 (Fed. Cir. 2001). A patent claim is not indefinite if "viewed in light of the specification and prosecution history," the claim "inform[s] those skilled in the art about the scope of the invention with reasonable certainty." Nautilus, 572 U.S. at 910. The definiteness requirement is analyzed "not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art." Energizer Holdings v. ITC, 435 F.3d 1366, 1370 (Fed. Cir. 2006). The definiteness requirement "ensure[s] that patent claims are written in such a way that they give notice to the public of what is claimed, thus enabling [others] to determine whether they infringe." Bayer Pharma AG v. Watson Labs., Inc., No. 12-1726-LPS, 2014 WL 4954617, at *3 (D. Del. Sept. 30, 2014).

A patent is "invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. BioSig Instruments, Inc.*, 572 U.S. 898, 901, 909-10(2014) (also noting that "the definiteness requirement must take into account the inherent limitations of language" as "absolute precision is unattainable.").

11. Enablement

Enablement requires that the specification of a patent teach a person skilled in the art how to make and use the claimed invention without undue experimentation. 35 U.S.C. § 112; In re Wands, 858 F.2d 731, 736-37 (Fed. Cir. 1988). The Federal Circuit has set forth eight factors that can be considered in the analysis of whether a patent is properly enabled: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *In re Wands*, at 737. These factors are "illustrative, not mandatory." *Amgen*, Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1213 (Fed. Cir. 1991). Further, "[t]he fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation must not be unduly extensive." PPG Industries, Inc. v. Guardian Industries Corp., 75 F.3d 1558, 1564 (Fed. Cir. 1996) (internal quotations and citations omitted). The consideration of whether experimentation is undue "is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." Id.; see also Cephalon, Inc. v. Watson Pharms., Inc., 707 F. 3d 1330, 1338-39 (Fed. Cir. 2013) ("extensive experimentation does not necessarily render the experiments unduly extensive where the experiments involve repetition of known or commonly used techniques."). The patentee is also not required to "describe how to make and use every possible variant of the claimed invention." AK Steel Corp. v. Sollac & Ugine, 344 F.3d 1234 (Fed. Cir. 2003).

B. Attorney's Fees And Costs³

Labcorp incorporates its statement in Parts I.C.1.iii & v. See supra.

³ Defendant bears the burden of proving it is entitled to any alleged remedies, including whether it is entitled to costs and attorneys' fees under 35 U.S.C. § 285. Labcorp, to the extent necessary, will introduce evidence to rebut Defendant's assertion that it are entitled to any remedies, including whether it is entitled to costs and attorneys' fees under 35 U.S.C. § 285.

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

C.A. No. 21-cv-669-GBW

C.A. No. 21-cv-1635-GBW

EXHIBIT 5: DEFENDANT'S STATEMENT OF ISSUES OF LAW <u>THAT REMAIN TO BE LITIGATED</u>

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Natera respectfully submits the following issues of law that remain to be litigated. This statement is based on Natera's claims, counterclaims, and defenses, Natera's current understanding of Plaintiff's claims and defenses, and the proceedings in this action to date. Should the Court determine that any issue identified in this list is more properly considered an issue of fact, it shall be so considered and Natera incorporates such issue into Natera's Statement of Issues of Fact That Remain to Be Litigated (Ex. 3 to Proposed Final Pretrial Order). To the extent that Natera's Statement of Issues of Fact That Remain to be Litigated contains issues that the Court deems to be issues of law, those issues are incorporated herein by reference. Natera reserves the right to revise, modify, supplement, or change the issues of law to be litigated in response to subsequent Court rulings and/or Labcorp's revised identification of issues of law and fact to be litigated or any new issues Labcorp may raise, or for other good cause. The following statement of issues of law is not exhaustive, and Natera reserves the right to prove any matters identified in the pleadings, and discovery responses, including in its contentions, interrogatory responses, expert reports, by experts at depositions, and by fact witnesses at depositions. Natera further intends to offer evidence to rebut evidence offered by Labcorp. By identifying the following issues, Natera does not necessarily concede that each of these issues, in whole or in part, is a pure issue of law. Further, insofar as the following issues, as a matter of law and precedent, themselves turn on additional or subsidiary legal issues or elements, those legal issues or elements are incorporated.

I. <u>INVALIDITY OF THE ASSERTED PATENTS</u>

Natera provides the below issues to be litigated and legal authorities.

A. Issues of Law to Be Litigated

1. Whether Natera has proven by clear and convincing evidence that claims 1–13 and 15–16 of the '799 Patent, claims 1–13 and 15–18 of the '863 Patent, and claims 1, 4–9, 12, and 15–27 of the '308 Patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

2. Whether Natera has proven by clear and convincing evidence that the asserted prior art qualifies as prior art under 35 U.S.C. § 102.

B. Person of Ordinary Skill in the Art

3. "The 'person of ordinary skill in the art' is a theoretical construct." *eSpeed, Inc. v. Brokertec USA, L.L.C.*, 404 F. Supp. 2d 575, 579 (D. Del. 2005) (quoting *Endress + Hauser, Inc. v. Hawk Measurement Sys. Pty. Ltd.*, 122 F.3d 1040, 1042 (Fed. Cir. 1997)). "Factors that may be considered in determining the ordinary level of skill in the art include: 1) the types of problems encountered in the art; 2) the prior art solutions to those problems; 3) the rapidity with which innovations are made; 4) the sophistication of the technology; and 5) the educational level of active workers in the field. 'Not all such factors may be present in every case, and one or more of them may predominate." *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 666–67 (Fed. Cir. 2000) (quoting *Custom Accessories, Inc. v. Jeffrey–Allan Indus., Inc.*, 807 F.2d 955, 962 (Fed. Cir. 1986)). The hypothetical person of ordinary skill in the art is presumed to know all of the teachings of the prior art references in the field of the invention at the time the invention was made. *See Union Carbide Corp. v. Am. Can Co.*, 724 F.2d 1567, 1576 (Fed. Cir. 1984).

C. Presumption of Validity

4. Patents are presumed to be valid. 35 U.S.C. § 282. "The presumption is, like all presumptions in law, a starting place and a procedural device assigning the burden of proof. To treat the presumption as irrebuttable would be to oust the courts of their jurisdiction to consider a challenge to the validity of patents before them." *Chore-Time Equip., Inc. v. Cumberland Corp.*, 713 F.2d 774, 780 (Fed. Cir. 1983). A challenger must prove by clear and convincing evidence that a patent is invalid. *Microsoft Corp. v. 141 Ltd. P'ship*, 564 U.S. 91, 111 (2011).

D. Priority Date

- 5. Labcorp "bears the burden of establishing that its claimed invention is entitled to an earlier priority date than an asserted prior art reference." *In re Magnum Oil Tools Int'l, Ltd.*, 829 F.3d 1364, 1376 (Fed. Cir. 2016). "To obtain the benefit of the filing date of a parent application, the claims of the later-filed application must be supported by the written description in the parent 'in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." *Anascape, Ltd. v. Nintendo of Am., Inc.*, 601 F.3d 1333, 1335 (Fed. Cir. 2010) (quoting *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)).
- 6. To claim a priority date earlier than the effective filing date of a patent application, the patentee must establish conception and "reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application." *In re Steed*, 802 F.3d 1311, 1316 (Fed. Cir. 2015) (internal quotations and citations omitted). Labcorp bears the burden of proving that any patent claim is entitled to a priority date earlier than its effective filing date. *See PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1305–06 (Fed. Cir. 2008).
- 7. Conception requires "formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." *Burroughs Wellcome Co. v. Barr Lab'ys., Inc.*, 40 F.3d 1223, 1228 (Fed. Cir. 1994). To establish conception, a party must show possession of every feature recited in the claim, and that every limitation of the claim was known to the inventor at the time of the alleged conception. *See Coleman v. Dines*, 754 F.2d 353, 359 (Fed. Cir. 1985). Conception may not be complete if those skilled in the art express uncertainty that "undermines the specificity of the inventor's idea that it

is not yet a definite and permanent reflection of the complete invention as it will be used in practice." *Burroughs Wellcome Co.*, 40 F.3d at 1229.

8. A party seeking to prove its entitlement to an earlier priority date, where it claims it is "first to conceive but second to reduce to practice," must also "demonstrate reasonable diligence toward reduction to practice." *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1578 (Fed. Cir. 1996). To establish actual reduction to practice, the party asserting an earlier priority date "must satisfy a two-prong test: (1) the party constructed an embodiment or performed a process that met every element of the [claim], and (2) the embodiment or process operated for its intended purpose." *Eaton v. Evans*, 204 F.3d 1094, 1097 (Fed. Cir. 2000). Actual reduction to practice requires that "the constructed embodiment or performed process include the precise elements recited" in the claims. *See id.* Thus, "there can be no actual reduction to practice if the constructed embodiment or performed process lacks an element recited in the [claims] or uses an equivalent of that element." *Id.* Moreover, there must be "some recognition of successful testing prior to the critical date for an invention to be reduced to practice." *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 593 (Fed. Cir. 1997).

E. Prior Art Before a Patent Examiner

9. "A court is not bound by the PTO's actions and must make its own independent determination of patent validity." *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1322 (Fed. Cir. 2005); *see Gardner v. TEC Sys., Inc.*, 725 F.2d 1338, 1345 (Fed. Cir. 1984); *see also Athletic Alternatives, Inc. v. Benetton Trading USA, Inc.*, 174 F. App'x 571, 574 (Fed. Cir. 2006) (holding that a court has a right to consider prior art that was before an examiner).

F. Patent Eligibility

10. Patent eligibility under 35 U.S.C. § 101 is "ultimately an issue of law" that "may contain underlying issues of fact." *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1365 (Fed. Cir. 2018),

cert. denied, 140 S. Ct. 911 (2020). Patent eligibility is governed by the two-step analysis in Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 217-18 (2014). Step one of the Alice inquiry asks whether the patent claims are directed to ineligible subject matter, e.g., an abstract idea. See Berkheimer, 881 F.3d at 1366. If the claims are directed to an abstract idea, then at step two the Court determines whether the claims include an "inventive concept sufficient to transform the abstract idea into a patent-eligible application." *Id.* at 1369. The Court "consider[s] the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." Alice, 573 U.S. at 217 (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 78– 79 (2012)). Where the "additional features" recite nothing more than "well-understood, routine, conventional activity," the claim is ineligible for patenting. Intellectual Ventures I LLC v. Erie Indemnity Co., 850 F.3d 1315, 1328 (Fed. Cir. 2017); see, e.g., Digitech Image Techs., LLC v. Elecs. For Imaging, Inc., 758 F.3d 1344, 1351 (Fed. Cir. 2014) (claim reciting "taking two data sets and combining them into a single data set" was directed to an abstract idea because the data sets were drawn from "existing information" and simply organized "into a new form"); see also RecogniCorp, LLC v. Nintendo Co., 855 F.3d 1322, 1327 (Fed. Cir. 2017) (claims that recited "a process that started with data, added an algorithm, and ended with a new form of data" were directed to an abstract idea); Berkheimer, 881 F.3d at 1366 (claims "directed to the abstract idea of parsing, comparing, storing, and editing data"); Elec. Power Group, LLC v. Alstom S.A., 830 F.3d 1350, 1353 (Fed. Cir. 2016) (claims focused on "collecting information, analyzing it, and displaying certain results of the collection and analysis" directed to an abstract idea). It is not enough "to merely improve a fundamental practice or abstract process by invoking a computer merely as a tool." Customedia Techs., LLC v. Dish Network Corp., 951 F.3d 1359, 1364 (Fed.

Cir. 2020) (citing Affinity Labs. of Texas, LLC v. DIRECTV, LLC, 838 F.3d 1253, 1258 (Fed. Cir. 2016)). Claims are ineligible where they are "merely implemented 'using some unspecified, generic computer' and [do] not 'purport to improve the functioning of the computer itself." Customedia, 951 F.3d at 1362 (quoting Alice, 573 U.S. at 225–26); see, e.g., Univ. of Fla. Rsch. Found., Inc. v. Gen. Elec. Co., 916 F.3d 1363, 1367 (Fed. Cir. 2019) (rejecting "do it on a computer" patents that merely sought "to automate 'pen and paper methodologies' to conserve human resources and minimize errors"); accord, e.g., In re Stanford, 991 F.3d 1245, 1250-51 (Fed. Cir. 2021) (claims were abstract because focused on "the use of mathematical calculations and statistical modeling" to manipulate genetic data and were not drawn to any "practical, technological improvements extending beyond improving the accuracy of a mathematically calculated statistical prediction"); Accenture Glob. Servs., GmbH v. Guidewire Software, Inc., 728 F.3d 1336, 1339, 1342 (Fed. Cir. 2013); Intell. Ventures I LLC v. Symantec Corp., 838 F.3d 1307, 1318-19 (Fed. Cir. 2016) (holding the mere application of a generic computer is not a technological improvement); In-Depth Test, LLC v. Maxim Integrated Prods., Inc., C.A. Nos. 14-887-CFC, 114-888-CFC, 2018 WL 6617142, at *4 (D. Del. Dec. 18, 2018) (citing Enfish, LLC v. Microsoft Corp., 822 F.3d 1327, 1334 (Fed. Cir. 2016)).

G. Anticipation

11. "Anticipation is an issue of fact." *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). Under pre-AIA 35 U.S.C. § 102(a), a patent claim is invalid if it is not novel, including if "the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent." Under 35 U.S.C. § 102(b), a patent claim is invalid if "the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." Under 35 U.S.C.

§ 102(e)(2), a patent claim is invalid as anticipated if the invention was described in "a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent." A patent claim is anticipated under 35 U.S.C. § 102(g)(2) where, before the applicant's invention thereof, "the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it."

- 12. A patent claim is anticipated if "a single prior art reference discloses, either expressly or inherently, each limitation of the claim." *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002); *see, e.g., Billups-Rothenberg, Inc. v. Assoc. Reg'l & Univ. Pathologists, Inc.*, 642 F.3d 1031, 1038 (Fed. Cir. 2011) ("A patent claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference."); *Schering Corp. v. Geneva Pharms.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003) ("[A] prior art reference which expressly or inherently contains each and every limitation of the claimed subject matter anticipates and invalidates."). A patent claim may therefore be anticipated even if a prior-art reference does not expressly point out each limitation of the claim. *Id.* Such inherent disclosure does not need to be recognized by a person of ordinary skill in the art if practice of the prior art inevitably produces the claimed feature. *In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1373 (Fed. Cir. 2007); *Abbott Labs. v. Baxter Pharm. Prods. Inc.*, 471 F.3d 1363, 1368 (Fed. Cir. 2006) ("Inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure.") (citation omitted).
- 13. "Anticipation is a question of fact that considers whether a single reference describes the claimed invention 'with sufficient precision and detail to establish that the subject matter existed in the prior art." *In re ThermoLife Int'l LLC*, 796 F. App'x 726, 730 (Fed. Cir. 2020) (quoting *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1120 (Fed. Cir. 2002)). "[A]

reference can anticipate a claim even if it 'd[oes] not expressly spell out' all the limitations arranged or combined as in the claim, if a person of skill in the art, reading the reference, would 'at once envisage' the claimed arrangement or combination." *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1341 (Fed. Cir. 2016) (quoting *In re Petering*, 301 F.2d. 676, 681 (C.C.P.A. 1962)).

- 14. "As long as the reference discloses all of the claim limitations and enables the 'subject matter that falls within the scope of the claims at issue,' the reference anticipates—no 'actual creation or reduction to practice' is required." *In re Gleave*, 560 F.3d 1331, 1334 (Fed. Cir. 2009) (quoting *Schering*, 339 F.3d at 1380–81). "This is so despite the fact that the description provided in the anticipating reference might not otherwise entitle its author to a patent." *Id.*; *see also Duke Univ. v. BioMarin Pharm. Inc.*, 685 F. App'x 967, 973 (Fed. Cir. 2017) ("An anticipatory reference must be enabled, but no actual creation or reduction to practice is required.") (quotations omitted). A "prior art reference need not demonstrate utility in order to serve as an anticipating reference under section 102." *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1326 (Fed. Cir. 2005).
- 15. Patent claims may be anticipated by prior art products or systems that are capable of performing the functions or methods covered by a patent claim, or publications describing the same. See, e.g., In re Hallman, 655 F.2d 212, 215 (C.C.P.A. 1981); see, e.g., Lockwood, 107 F.3d at 1570 (holding software was prior art under pre-AIA Sections 102(a) and (b)); Alexsam, Inc. v. Gap, Inc., 621 F. App'x 983, 988–89 (Fed. Cir. 2015) (reversing JMOL of no anticipation under pre-AIA Section 102(g) based on "electronic gift card system" prior art). Patent claims may also be anticipated by prior art products or systems that would infringe if they did not pre-date the priority date of the patent, because "[t]hat which infringes if later anticipates if earlier." Brown v. 3M, 265 F.3d 1349, 1352 (Fed. Cir. 2001). It is well settled that multiple pieces of evidence may

be relied upon to prove that a single prior-art product or system anticipates under 35 U.S.C. §§ 102(a) and (g). *See IOENGINE, LLC v. PayPal Holdings, Inc.*, 607 F. Supp. 3d 464, 518–19 (D. Del. 2022) ("[I]t is permissible for a defendant to establish anticipation by using several documents that reveal how a single prior art system works."); *see also Finjan, Inc. v. Symantec Corp.*, C.A. No. 10-593-GMS, 2013 WL 5302560, at *17 (D. Del. Sept. 19, 2013), *aff'd*, 577 F. App'x 999 (Fed. Cir. 2014) (rejecting challenge that defendant relied on "distinct pieces of prior art that cannot be characterized as a single product" because they were used "simply to demonstrate and support how [the prior-art product] functioned at the time, not as distinct references").

16. A patent claim may also be invalid under § 102 in view of prior public knowledge or use of the relevant patented features. See UCB, Inc. v. Watson Labs., Inc., 927 F.3d 1272, 1289– 91 (Fed. Cir. 2019); see also, e.g., Novo Nordisk Pharm., Inc. v. Bio-Tech. Gen. Corp., 424 F.3d 1347, 1355–56 (Fed. Cir. 2005) (affirming finding of anticipation under § 102(a) based on enabling disclosure in prior printed publication); BroadSoft, Inc. v. CallWave Commc'ns, LLC, 282 F. Supp. 3d 771, 790–91 (D. Del. 2017) (holding prior art software system anticipated patents because relevant features were publicly known and on sale before critical date); UCB, Inc. v. Actavis Labs., UT, Inc., C.A. No. 19-474-KAJ, 2021 U.S. Dist. LEXIS 90952, at *62–63 (D. Del. Mar. 26, 2021); Gillette Co. LLC v. Dollar Shave Club, Inc., C.A. No. 15-1158-LPS-CJB, 2019 U.S. Dist. LEXIS 46865, at *6–7 (D. Del. Mar. 21, 2019). "Prior knowledge and use by a single person is sufficient" to defeat patentability under Section 102(a). UCB, 927 F.3d at 1289 (quoting Coffin v. Ogden, 85 U.S. 120, 124 (1873)). "[T]he 'known or used' prong of [pre-AIA] Section 102(a) [] mean[s] 'knowledge or use which is accessible to the public." BASF Corp. v. SNF Holding Co., 955 F.3d 958, 964 (Fed. Cir. 2020) (quoting Carella v. Starlight Archery & Pro Line Co., 804 F.2d 135, 139 (Fed. Cir. 1986)); see also MPEP § 2132 at I.A. Actual public use or knowledge is not required,

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 83 of 739 PageID #: 12833

Exhibit 5

and the invention need only be "publicly accessible," *i.e.*, accessible to the public "upon reasonable inquiry." *BASF Corp.*, 804 F.3d at 965.

- 17. Public use includes "any use of [the claimed] invention by a person other than the inventor who is under no limitation, restriction, or obligation of secrecy to the inventor." *Netscape Commc'ns Corp. v. Konrad*, 295 F.3d 1315, 1320 (Fed. Cir. 2002) (quoting *Petrolite Corp. v. Baker Hughes Inc.*, 96 F.3d 1423, 1425 (Fed. Cir. 1996)). A product is "on sale" if it satisfies the two-part test set forth in *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998), namely, whether the claimed invention was (1) the subject of a commercial offer for sale; and (2) ready for patenting at the time of that offer for sale. *See Meds. Co. v. Hospira, Inc.*, 827 F.3d 1363, 1368 (Fed. Cir. 2016) (en banc) (citing *Pfaff*, 525 U.S. at 67–68). Whether a patent is invalid for a public use or on sale is a question of law based on the underlying facts. *Id.* at 1371; *see also Pronova BioPharma Norge AS v. Teva Pharm. USA, Inc.*, 549 F. App'x 934, 938–39 (Fed. Cir. 2013).
- 18. To the extent the Asserted Claims are entitled to an effective filing date before March 16, 2013, under pre-AIA 35 U.S.C. § 102(g), "[a] person shall be entitled to a patent unless . . . before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." A patent claim may therefore be invalidated by the prior invention of another. *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1035 (Fed. Cir. 2001); *see also, e.g., TC Tech., LLC v. Sprint Corp.*, 379 F. Supp.3d 305, 318 (D. Del. 2019) (citing *Solvay S.A. v. Honeywell Int'l, Inc.*, 742 F.3d 998, 1000 (Fed. Cir. 2014)). The party asserting invalidity "need only prove either that they first reduced the invention to practice, or that [the prior inventor] conceived of the invention first and were diligent in reducing it to practice." *bioMerieux, S.A. v. Hologic, Inc.*, C.A. No. 18-21-LPS, 2020 U.S. Dist. LEXIS 25318, at *29–30 (D. Del. Feb. 7, 2020) (citing *Fox Grp., Inc. v. Cree, Inc.*, 700 F.3d 1300, 1304 (Fed.

Cir. 2012)); see also, e.g., Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc., 774 F.3d 968, 974–75 (Fed. Cir. 2014). Moreover, where the prior inventors are "non-parties and their testimony concern[s] an unpatented prior invention" the corroboration rule—requiring corroboration of inventor testimony directed to establishing their invention as anticipating the claims at issue—is not triggered because "this [situation] does not rise to the level of self-interest required to justify triggering application of the corroboration rule." Thomson, S.A. v. Quixote Corp., 166 F.3d 1172, 1175–76 (Fed. Cir. 1999).

H. Obviousness

- 19. "Obviousness is a question of law based on underlying findings of fact." *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1237 (Fed. Cir. 2010). "These underlying factual determinations include: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) the extent of any proffered objective indicia of nonobviousness," termed "secondary considerations." *Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1334 (Fed. Cir. 1998) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18, 86 S. Ct. 684, 694 (1966)).
- 20. Under 35 U.S.C. § 103, a patent claim is invalid if the "differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." As the Supreme Court held in *KSR Int'l Co. v. Teleflex Inc.*:

Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

550 U.S. 398, 406 (2007) (quoting *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)); see also Allergan, Inc. v. Sandoz Inc., 796 F.3d 1293, 1303 (Fed. Cir. 2015). That is, "[w]hen a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability." Id. at 417. Moreover, "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." Id. A "combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." Id. at 416. The Supreme Court reasoned: "[g]ranting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their value or utility." Id. at 419.

21. Obviousness may be based on one or more references, although either the prior art as a whole, or knowledge generally available to one of ordinary skill in the art, may suggest the obviousness of combining and modifying the prior art to arrive at the claimed invention. *See SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356 (Fed. Cir. 2000); *see also KSR*, 550 U.S. at 420. "As long as some motivation or suggestion to combine the references is provided by the prior art taken as a whole, the law does not require that the references be combined for the reasons contemplated by the inventor." *In re Beattie*, 974 F.2d 1309, 1312 (Fed. Cir. 1992). It is sufficient that a combination of elements was "obvious to try" because "[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 86 of 739 PageID #: 12836

Exhibit 5

technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." *KSR*, 550 U.S. at 421. Indeed, "in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.* at 420. "In that instance the fact that a combination was obvious to try might show that it was obvious under § 103." *Id.* It is established that "a rejection for obviousness under § 103 can be based on a reference which happens to anticipate the claimed subject matter." *In re application of Meyer*, 599 F.2d 1026, 1031 (C.C.P.A. 1979).

- 22. "[T]he ultimate determination of obviousness 'does not require absolute predictability of success. ... [A]ll that is required is a reasonable expectation of success." *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1125 (Fed. Cir. 2000). The factfinder inquires whether a person of ordinary skill in the art would have been motivated to combine the prior art in the manner claimed and would have had a reasonable expectation of success in doing so. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1366–67 (Fed. Cir. 2016). The Federal Circuit's "case law does not require that a particular combination must be the preferred, or the most desirable, combination described in the prior art in order to provide motivation for the current invention." *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004). Moreover, "[c]onclusive proof of efficacy is not necessary to show obviousness. All that is required is a reasonable expectation of success." *Hoffmann-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1331 (Fed. Cir. 2014); *see also Valeant Pharm. Int'l, Inc. v. Mylan Pharm. Inc.*, 955 F.3d 25, 34 (Fed. Cir. 2020).
- 23. The factfinder may also consider whether there is a "showing of a suggestion, teaching, or motivation to combine the prior art references." *See Brown & Williamson Tobacco Corp.*, 229 F.3d at 1124; *see also KSR*, 550 U.S. at 419. A "suggestion, teaching, or motivation

to combine the relevant prior art teachings to achieve the claimed invention does not have to be found explicitly in the prior art references sought to be combined, but rather 'may be found in any number of sources, including common knowledge, the prior art as a whole, or the nature of the problem itself." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1362 (Fed. Cir. 2007) (citations omitted). Multiple references can be combined to show a patent is invalid, provided a prima facie case is shown and there is motivation to combine the references such that a person skilled in the art would be able to make the claimed invention. *See In re Kahn*, 441 F.3d 977, 988–91 (Fed. Cir. 2006).

Examination Guidelines. *See* Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103, 72 Fed. Reg. 57526 (Oct. 10, 2007). These Guidelines identify various rationales under *KSR* for finding a claim obvious at the time of the filing of the application for the patent, including those based on other precedents, including but not limited to (1) combining prior art elements according to known methods to yield predictable results; (2) simple substitution of one known element for another to obtain predictable results; (3) use of known technique to improve similar devices (methods, or products) in the same way; (4) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (5) "[o]bvious to try"—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (6) known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art; and (7) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to

modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

25. Patent claims may be deemed obvious in light of prior art products or systems, or publications describing same, that are capable of performing the functions or methods covered by a patent claim. *See, e.g., In re Hallman*, 655 F.2d 212, 215, 210 U.S.P.Q. 609 (C.C.P.A. 1981).

I. Secondary Considerations of Nonobyiousness

- 26. "Once a prima facie case of obviousness has been established, the burden shifts to the applicant to come forward with evidence of secondary considerations of non-obviousness to overcome the prima facie case." *Aventis Pharma S.A. v. Hospira, Inc.*, 743 F. Supp. 2d 305, 344 (D. Del. 2010), *aff'd*, 675 F.3d 1324 (Fed. Cir. 2012). "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." *KSR Int'l Co.*, 550 U.S. at 406 (quoting *Graham*, 383 U.S. at 17–18).
- strong prima facie case of obviousness." *Wyers*, 616 F.3d at 1246. Once a challenger has put forth a prima facie case of invalidity, a patentee can proffer evidence of secondary considerations by a preponderance of evidence. *See Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1053 (Fed. Cir. 2016) (en banc); *see also Hospira, Inc. v. Amneal Pharm., LLC*, 285 F. Supp. 3d 776, 784 (D. Del. 2018), *appeal dismissed*, C.A. No. 2018-1522, 2018 WL 4382057 (Fed. Cir. June 25, 2018), *and aff'd*, 748 F. App'x 1024 (Fed. Cir. 2019) ("There must be enough evidence, however, for a finding that a given secondary consideration, if presented, exists by a preponderance of the evidence. If

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 89 of 739 PageID #: 12839

Exhibit 5

there is, then the probative value of each secondary consideration will be considered in light of the evidence produced."); *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1366 (Fed. Cir. 2001) (allegedly copied feature must be an embodiment of the patented claims).

- 28. "The patentee bears the burden of showing that a nexus exists" between the alleged secondary considerations of nonobviousness and the patented invention. Fox Factory, Inc. v. SRAM, LLC, 944 F.3d 1366, 1373 (Fed. Cir. 2019). "[C]ase law clearly establishes that the patentee must establish a nexus between the evidence of commercial success and the patented invention." Wyers, 616 F.3d at 1246. "So too if the feature that creates the commercial success was known in the prior art, the success is not pertinent." Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1312 (Fed. Cir. 2006). "When the thing that is commercially successful is not coextensive with the patented invention—for example, if the patented invention is only a component of a commercially successful machine or process, the patentee is not entitled to a presumption of nexus." Fox Factory, 944 F.3d at 1373 (internal citations omitted). "A patent claim is not coextensive with a product that includes a 'critical' unclaimed feature that is claimed by a different patent and that materially impacts the product's functionality." Id. at 1375. Similarly, nexus must be shown between the "merits of the claimed invention" and the evidence of long-felt need. Merck Sharp & Dohme Corp. v. Hospira Inc., C.A. No. 14-915-RGA, 2016 WL 5872620, at *11 (D. Del. July 10, 2016), aff'd, 874 F.3d 724 (Fed. Cir. 2017). Nexus must also be shown "between industry praise and the patented technology." Alarm.com, Inc. v. SecureNet Techs. LLC, C.A. No. 15-807-RGA, 2019 WL 133228, at *4 (D. Del. Jan. 8, 2019) (emphasis in original).
- 29. The patentee bears the burden of demonstrating that the relevant commercial success is attributable to the claimed invention "as opposed to other economic and commercial

factors unrelated to the technical quality of the patented subject matter." Cable Elec. Prods, Inc. v. Genmark, Inc., 770 F. 2d 1015, 1027 (Fed. Cir. 1987); see Windsurfing Int'l Inc. v. AMF, 782 F. 2d 995, 999-1000 (Fed. Cir. 1986) (considerations such as intervening, non-covered technological innovations, popularity of accessories, and advertising expense are all relevant to the nexus determination). "If commercial success is due to an element in the prior art, no nexus exists." Tokai Corp. v. Easton Enters., Inc., 632 F.3d 1358, 1369-70 (Fed. Cir. 2011); see, e.g., In re Huai-Hung Kao, 639 F.3d 1057, 1068 (Fed. Cir. 2011) ("Where the offered secondary consideration actually results from something other than what is both claimed and novel in the claim, there is no nexus to the merits of the claimed invention.") (emphasis in original); Ormco, 463 F.3d at 1312 ("[I]f the feature that creates the commercial success was known in the prior art, the success is not pertinent."). Similarly, the patentee must show alleged industry praise is due to the allegedly novel features of the Asserted Claims, rather than to features present in the prior art. See Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318, 1328 (Fed. Cir. 2008). Evidence of unexpected results must tend to "establish that there is a difference between the results obtained and those of the closest prior art, and that the difference would not have been expected by one of ordinary skill in the art at the time of the invention." Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc., 752 F.3d 967, 977 (Fed. Cir. 2014).

J. Written Description

30. The written description requirement mandates that "[t]he specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112, ¶ 1. "A determination that a patent is invalid for failure to meet the written description requirement of

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 91 of 739 PageID #: 12841

Exhibit 5

35 U.S.C. § 112, ¶ 1 is a question of fact." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1355 (Fed. Cir. 2010) (en banc).

- 31. The written description, drawings, and claims in a patent must clearly allow a person of ordinary skill in the art to understand and recognize that the patentee invented what is claimed. Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 1479 (Fed. Cir. 1998). In this regard, the patent must demonstrate by disclosure in the specification to those skilled in the art that the patentee had "possession" of what is now asserted to be the claimed invention. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1561 (Fed. Cir. 1991). The written description must actually or inherently disclose every claim element. PowerOasis, Inc. v. T-Mobile USA, Inc., 522 F.3d 1299, 1306–07 (Fed. Cir. 2008). It is not enough to say that undisclosed subject matter would have been obvious or within the normal skill set of a person of ordinary skill. ICU Med., Inc. v. Alaris Med. Sys., Inc., 558 F.3d 1368, 1377 (Fed. Cir. 2009). A written description that discloses only a certain method does not "necessarily support a broad claim as to every possible type of [method], no matter how different in structure or operation from the inventor's [discussion]." LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1346 (Fed. Cir. 2005). That is, an inventor's description of one type of method does not entitle the inventor to claim "any and all means for achieving that objective." *Id.*; see also ICU Med., 558 F.3d at 1377–79.
- 32. For the written description requirement, "the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). Possession requires a "show[ing] that the inventor actually invented the invention claimed." *Id.* The "level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims

and on the complexity and predictability of the relevant technology." *Id.* "[T]he purpose of the written description requirement is to 'ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." *ICU Med.*, 558 F. 3d at 1376–79 (citations omitted).

33. The use of patentee's contention that the claims cover the accused product may be used to illustrate the breadth of the claims and lack of support. See Rivera v. ITC, 857 F.3d 1315, 1319–21 (Fed. Cir. 2017) ("Thus, even applying the 'broad' definition of 'pod' . . . written description support for broad claims covering a receptacle with integrated filter such as Solofill's accused products and [the patent holder's products] is lacking."). The written description requirement is not satisfied where one example is described but it is "not representative of the full variety or scope of the genus." AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d 1285, 1300–01 (Fed. Cir. 2014); see e.g., Amgen Inc. v. Sanofi, 872 F.3d 1367, 1374 (Fed. Cir. 2017) (permissible to use the accused product to show that the specification examples are "not representative of the entire genus."). "Post-priority-date evidence can be considered where . . . it is used to evaluate whether the disclosed species sufficiently represent the claimed genera." MorphSys, Inc. v. Janssen Biotech, Inc., 358 F. Supp. 3d 354, 365 (D. Del. 2019). Even if a patent contains working examples, there must be "meaningful guidance" to provide adequate written description. See Idenix Pharm. LLC v. Gilead Scis. Inc., 941 F.3d 1149, 1164-65 (Fed. Cir. 2019).

K. Indefiniteness

34. Where the claims of a patent, read in light of its specification and prosecution history, fail to inform those skilled in the art about the scope of the invention with reasonable certainty, such claims are invalid under 35 U.S.C. § 112 for indefiniteness. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). Indefiniteness is a question of law which may be

based on underlying facts. *See Berkheimer*, 881 F.3d at 1368 (Fed. Cir. 2018). To determine whether a claim is indefinite, the court looks to "the claims, specification, and prosecution history—to ascertain if they convey to one of skill in the art with reasonable certainty the scope of the invention claimed." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015).

35. A claim may be indefinite where elements specified by the claim may be measured or assessed by a variety of means, none of which are written into the claim. *Media Rights Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1371 (Fed. Cir. 2015) (quoting *Nautilus, Inc.*, 572 U.S. at 911). In such instances, where something falls within the scope of the claim when assessed or measured by one means, but is excluded from the scope of the claim when assessed or measured by another means, the claim is invalid for indefiniteness. *Dow Chem. Co. v. NOVA Chems. Corp.* (*Canada*), 803 F.3d 620, 634–35 (Fed. Cir. 2015); *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1344–45 (Fed. Cir. 2015). "[P]atent claims with descriptive words or terms of degree must provide objective boundaries for those of skill in the art in the context of the invention to be definite." *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 30 F.4th 1339, 1349 (Fed. Cir. 2022).

L. Enablement

- 36. "Enablement is a question of law based on underlying factual findings." *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012). To satisfy the enablement requirement, the specification of a patent must enable a person of skill in the art, as of the filing date, to practice the full scope of the claimed invention without undue experimentation. *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 941–42 (Fed. Cir. 2010); *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008).
- 37. "Enabling the full scope of each claim is part of the quid pro quo of the patent bargain." *Id.* at 999 (quoting *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003)

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 94 of 739 PageID #: 12844

Exhibit 5

(quotations omitted)). If a patent enables some embodiments within the scope of a claim, but not others, then the claim is invalid. *ALZA*, 603 F.3d at 939–43 (affirming judgment that claims encompassing medicinal tablets in both osmotic and non-osmotic dosage forms were invalid where specification taught only osmotic dosage forms); *Sitrick*, 516 F.3d at 999–1001 (affirming summary judgment that claims encompassing both video games and movies held invalid where specification only taught use of invention in video games); *Auto. Tech. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1281–85 (Fed. Cir. 2007) (affirming summary judgment that claims encompassing both mechanical and electronic side-impact sensors were invalid where specification taught only mechanical sensors).

- 38. The focus of an enablement inquiry is on the teachings in the specification. *See* 35 U.S.C. § 112 ("The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same. . . ."). To satisfy the plain language of 35 U.S.C. § 112, the patentee is "required to provide an adequate enabling disclosure in the specification; it cannot simply rely on the knowledge of a person of ordinary skill to serve as a substitute for the missing information in the specification." *ALZA*, 603 F.3d at 941; *see also Auto. Tech.*, 501 F.3d at 1283–84 (claims encompassing electronic sensors held invalid despite the fact that known technologies could be used to create the electronic sensors, where specification did not teach electronic sensors).
- 39. The Federal Circuit has identified several factors, referred to as the *Wands* factors, that a court may consider when deciding whether the specification requires undue experimentation: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of

the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Amgen Inc. v. Sanofi, Aventisub LLC*, 987 F.3d 1080, 1084 (Fed. Cir. 2021), *aff'd sub nom. Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023) (citing *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)). "A court need not consider each of the *Wands* factors, for they 'are illustrative, not mandatory." *Baxalta Inc. v. Genentech, Inc.*, 579 F. Supp. 3d 595, 608 (D. Del. 2022), *aff'd*, 81 F.4th 1362 (Fed. Cir. 2023) (quoting *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991)). Moreover, "when there is no disclosure of any specific starting material or of any of the condition under which a process can be carried out, undue experimentation is required." *ALZA*, 603 F.3d at 941 (quoting *Auto. Tech.*, 501 F.3d at 1283–84).

II. REMEDIES AVAILABLE TO NATERA

A. Issues of Law to Be Litigated

- 40. Whether Natera has proven by a preponderance of the evidence that this is an exceptional case pursuant 35 U.S.C. § 285.
- 41. Whether Natera has proven by a preponderance of the evidence that it is entitled to attorneys' fees, expenses, or costs, and the amount.

B. Attorney's Fees and Costs

42. Under 35 U.S.C. § 285, "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." "An 'exceptional' case is simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated. District courts may determine whether a case is 'exceptional' in the case-by-case exercise of their discretion, considering the totality of the circumstances." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 554 (2014).

other than attorney's fees—should be allowed to the prevailing party." Fed. R. Civ. P. 54(d)(1); see also D. Del. L.R. 54.1(a). Costs include: "(1) Fees of the clerk and marshal; (2) Fees for printed or electronically recorded transcripts necessarily obtained for use in the case; (3) Fees and disbursements for printing and witnesses; (4) Fees for exemplification and the costs of making copies of any materials where the copies are necessarily obtained for use in the case; (5) Docket fees under section 1923 of this title; (6) Compensation of court appointed experts, compensation of interpreters, and salaries, fees, expenses, and costs of special interpretation services under section 1828 of this title." 28 U.S.C. § 1920; see also D. Del. L.R. 54.1 (b).

III. ALLEGED INFRINGEMENT OF THE ASSERTED PATENTS

A. Alleged Direct Infringement Under 35 U.S.C. § 271

- 44. Direct infringement occurs when "whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor" 35 U.S.C. § 271(a).
- 45. "Infringement, whether literal or under the doctrine of equivalents, is a question of fact." *Cook Biotech Inc. v. Acell, Inc.*, 460 F.3d 1365, 1373 (Fed. Cir. 2006). As noted *supra*, Natera discusses infringement in its discussion of legal issues herein to provide citations to relevant legal authority, without waiver of any argument regarding whether a particular issue is one of fact or law.
- 46. Direct infringement of a method claim requires the patentee to demonstrate that every step of the claimed method is practiced by the accused infringer. *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 30 F.4th 1339, 1351 (Fed. Cir. 2022); *see also Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1320 (Fed. Cir. 2009) ("Direct infringement requires a party to perform each and every step or element of a claimed method or product" (quotations and citations

- omitted).). "[A]n accused product or process is not infringing unless it contains each limitation of the claim, either literally or by an equivalent." *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1358 (Fed. Cir. 2005).
- 47. "[I]nfringement requires 'specific instances of direct infringement or that the accused device necessarily infringes the patent in suit." *Ball Aerosol & Specialty Container, Inc. v. Ltd. Brands, Inc.*, 555 F.3d 984, 995 (Fed. Cir. 2009) (*quoting ACCO Brands, Inc. v. ABA Locks Mfr. Co.*, 501 F.3d 1307, 1313 (Fed. Cir. 2007)). Labcorp's burden of proof is preponderance of the evidence. *See Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293, 1310 (Fed. Cir. 2005). "[W]hen no reasonable jury could find that every limitation recited in a properly construed claim is found in the accused device either literally or under the doctrine of equivalents," infringement may be decided as a matter of law. *Advanced Steel Recovery, LLC v. X-Body Equip., Inc.*, 808 F.3d 1313, 1317 (Fed. Cir. 2015) (internal citations omitted).
- 48. "[L]imitations cannot be read into the claims from the specification or the prosecution history." *Burke, Inc. v. Bruno Indep. Living Aids, Inc.*, 183 F.3d 1334, 1340 (Fed. Cir. 1999). "If an accused product does not infringe an independent claim, it also does not infringe any claim depending thereon." *Motivation Innovations LLC v. Ulta Salon Cosmetics & Fragrance Inc.*, 59 F. Supp. 3d 663, 669 (D. Del. 2014).

B. Doctrine of Equivalents

49. "[A] product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 21 (1997) (quoting Graver Tank & Mfg. Co. v. Linde Air Prods. Co., 339 U.S. 605, 609 (1950)). Infringement under the doctrine of equivalents is a question of fact. Stryker Corp. v. Davol Inc., 234 F.3d 1252, 1258 (Fed. Cir.

- 2000). The doctrine of equivalents is "a limited remedy available in special circumstances." *Schoell v. Regal Marine Indus., Inc.*, 247 F.3d 1202, 1210 (Fed. Cir. 2001).
- 50. The doctrine of equivalents (DOE) requires a claim limitation-by-limitation analysis. See Akzo Nobel Coatings, Inc. v. Dow Chem. Co., 811 F.3d 1334, 1342 (Fed. Cir. 2016). The patentee must prove by a preponderance of the evidence that each and every difference between the accused process and the literal scope of the claimed features is insubstantial. See Graver Tank & Mfg. Co., 339 U.S. at 608. The "all limitations" or "all-elements" rule "holds that an accused product or process is not infringing unless it contains each limitation of the claim, either literally or by an equivalent." Freedman Seating Co., 420 F.3d at 1358. A claim limitation's equivalent is found in an accused product only "where an equivalent differs from the claimed limitation only insubstantially." Enzo Biochem Inc. v. Applera Corp., 702 F. App'x 971, 976 (Fed. Cir. 2017) (internal citation and quotation omitted). "Whether a component in the accused subject matter performs substantially the same function as the claimed limitation in substantially the same way to achieve substantially the same result may be relevant to this determination." Id. (internal citation and quotation omitted).
- 51. A DOE argument must be established by claim-limitation-specific evidence, with analysis as to the substantial similarity between each specific claim limitation for which equivalency is alleged and the specific feature or operation of the allegedly infringing product or process that is accused for that claim limitation:

Such evidence must be presented on a limitation-by-limitation basis. Generalized testimony as to the overall similarity between the claims and the accused infringer's product or process will not suffice.

Tex. Instruments Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1567 (Fed. Cir. 1996).

52. A patentee cannot generically allege equivalence to a product as a whole, but must do so for each claim limitation, with particularized testimony and linking arguments as to how the accused product's features or operations are equivalent to each claim limitation for which equivalency is alleged. See Network Com., Inc. v. Microsoft Corp., 422 F.3d 1353, 1363 (Fed. Cir. 2005); Horizon Medicines LLC v. Alkem Lab'ys Ltd., 503 F. Supp. 3d 118, 148 (D. Del. 2020), aff'd, No. 2021-1480, 2021 WL 5315424 (Fed. Cir. Nov. 16, 2021) (finding no DOE infringement where plaintiff applied DOE theory to two claim limitations simultaneously); Galderma Lab'ys, L.P. v. Amneal Pharms. LLC, 806 F. App'x 1007, 1014 (Fed. Cir. 2020) (reversing judgment of DOE infringement because plaintiff relied on same testimony to support equivalency for two distinct limitations, thus failing to "present particularized testimony and linking argument" on a limitation-by-limitation basis); Inline Connection Corp. v. AOL Time Warner Inc., 364 F. Supp. 2d 417, 447-48 (D. Del. 2005) (granting summary judgment of no DOE infringement where plaintiff "impermissibly subsumed [its DOE arguments] in its arguments for literal infringement and provides insufficient particularized linking testimony to raise a genuine question of material fact"). Similarly, "[a] patentee, bearing the burden of showing equivalence, cannot merely point to other claim limitations to satisfy the doctrine of equivalents. Doing so runs afoul of the 'allelements rule' articulated in Warner-Jenkinson." Advanced Steel Recovery, LLC v. X-Body Equip., Inc., 808 F.3d 1313, 1320 (Fed. Cir. 2015); see also Cooper Notification, Inc. v. Twitter, Inc., 867 F. Supp. 2d 485, 496–97 (D. Del. 2012).

C. Claim Vitiation

53. As a matter of law, an element of an accused process cannot be deemed an equivalent if such a finding would entirely vitiate the claim limitation. *See Warner-Jenkinson*, 520 U.S. at 39 n.8 ("[I]f a theory of equivalence would entirely vitiate a particular claim element, partial or complete judgment should be rendered by the court, as there would be no further *material*

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 100 of 739 PageID #: 12850

Exhibit 5

issue for the jury to resolve.") (emphasis original); see also, e.g., Virnetx, Inc. v. Cisco Sys., Inc., 767 F.3d 1308, 1322–23 (Fed. Cir. 2014). A theory of infringement under the doctrine of equivalents "thus fails if it renders a claim limitation inconsequential or ineffective." Akzo, 811 F.3d at 1342; see also United Access Techs., LLC v. AT & T Corp., 265 F. Supp. 3d 446, 453 (D. Del. 2017) (Stark, J.), rev'd in part on other grounds by United Access Techs., LLC v. AT & T Corp., 757 Fed. App'x 960 (Fed. Cir. 2019). The doctrine applies equally to the Court's construction of a claim term as to the words written in the patent claims themselves. See Augme Techs., Inc. v. Yahoo! Inc., 755 F.3d 1326, 1332, 1335–37 (Fed. Cir. 2014); United Access Techs., 265 F. Supp. 3d at 453. Claim vitiation is "important to ensure that the application of [] [DOE], even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety." See Warner-Jenkinson, 520 U.S. at 29.

- 54. "The vitiation concept has its clearest application where the accused device contain[s] the antithesis of the claimed structure." *See Brilliant Instruments, Inc. v. GuideTech, LLC*, 707 F.3d 1342, 1347 (Fed. Cir. 2013) (citation omitted); *see also Abbott Lab'ys v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1211 (Fed. Cir. 2007) ("[T]he concept of equivalency cannot embrace a structure that is specifically excluded from the scope of the claims." (citation omitted)); *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1356 (Fed. Cir. 2012) ("[C]ourts properly refuse to apply the doctrine of equivalents where the accused device contain[s] the antithesis of the claimed structure." (citation omitted)).
- 55. "[V]itiation comes into play when the alleged equivalent is 'diametrically opposed' to the missing claim element." *Bio-Rad Lab'ys, Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1367 (Fed. Cir. 2020) (citation omitted); *see also, e.g., United Access Techs., LLC v. AT&T Corp.*, Nos. 2021-2002 & 2021-2007, 2022 WL 1124961, at *5 (Fed. Cir. Apr. 15, 2022) (affirming summary

judgment of no DOE infringement because theory "would 'embrace a structure that is specifically excluded from the scope of the claims" (citation omitted)); *EMED Techs. Corp. v. Repro-Med Sys., Inc.*, 809 F. App'x 885, 892 (Fed. Cir. 2020) (affirming summary judgment of no DOE infringement where alleged equivalent was excluded from the properly construed claim limitation); *XMTT, Inc. v. Intel Corp.*, C.A. No. 18-1810-MFK, 2023 WL 2163242, at *8 (D. Del. Feb. 22, 2023) (granting summary judgment of no DOE infringement because accused product performed the "antithesis" of the claimed element).

56. A patentee's theory of equivalence, in light of the claim language and alleged evidence of infringement, can itself mandate the legal conclusion that the alleged equivalent would vitiate the claim limitations. *See Warner-Jenkinson*, 520 U.S. at 39 n.8 ("[I]f a theory of equivalence would entirely vitiate a particular claim element, partial or complete judgment should be rendered by the court, as there would be no further material issue for the jury to resolve."); *Duncan Parking Techs., Inc. v. IPS Grp., Inc.*, 914 F.3d 1347, 1361–62 (Fed. Cir. 2019) (summary judgment of no infringement under DOE due to vitiation); *Rembrandt Pat. Innovations, LLC v. Apple, Inc.*, 716 F. App'x 965, 977–78 (Fed. Cir. 2017) (same).

D. Ensnarement

- 57. "The doctrine of equivalents cannot be applied to encompass the prior art as 'this court has consistently limited the doctrine of equivalents to prevent its application to ensnare prior art." *Gemalto S.A. v. HTC Corp.*, 754 F.3d 1364, 1374–75 (Fed. Cir. 2014) (citations omitted). "This limitation is imposed even if a jury has found equivalence as to each claim element." *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1322–23 (Fed. Cir. 2009) (citations omitted).
- 58. To test whether an alleged equivalent would ensuare the prior art, "[a] hypothetical claim may be constructed to literally cover the accused device. If such a claim would be

unpatentable under 35 U.S.C. §§ 102 or 103, then the patentee has overreached, and the accused device is noninfringing as a matter of law." *Interactive Pictures Corp. v. Infinite Pictures, Inc.*, 274 F.3d 1371, 1380 (Fed. Cir. 2001) (internal citations omitted).

IV. ALLEGED REMEDIES SOUGHT BY LABCORP

A. Issues of Law to Be Litigated

- 59. If the Asserted Claims are found valid and infringed, whether Labcorp has proven by a preponderance of the evidence that it is entitled to damages, in the form of lost profits, a reasonable royalty, pre-judgment and/or post-judgment interest, and attorneys' fees and costs.
- 60. If the Asserted Claims are found valid and infringed, whether Labcorp has proven by a preponderance of the evidence that it is entitled to a permanent injunction.

B. Damages in General

61. Under 35 U.S.C. § 284, upon a finding of infringement, "the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court." "[T]he amount of a prevailing party's damages is a finding of fact on which the plaintiff bears the burden of proof by a preponderance of the evidence." *Smithkline Diagnostics, Inc. v. Helena Labs. Corp.*, 926 F.2d 1161, 1164 (Fed. Cir. 1991). It is plaintiff's initial burden to prove damages, including to apportion any proposed royalty so that it reflects "the value attributable to the infringing features of the product, and no more." *See Ericsson, Inc. v. D–Link Sys., Inc.*, 773 F.3d 1201, 1226 (Fed. Cir. 2014); *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 872 (Fed. Cir. 2010) ("But it was ResQNet's burden, not Lansa's, to persuade the court with legally sufficient evidence regarding an appropriate reasonable royalty."); *W.L. Gore & Assocs. v. C.R. Bard, Inc.*, 2015 WL 12731924, at *4, *6–7 (D. Del. Nov. 4, 2015).

C. Lost Profits

- 62. "To recover lost profits, the patent owner must show 'causation in fact,' establishing that 'but for' the infringement, he would have made additional profits." *Grain Processing Corp. v. Am. Maize-Prod. Co.*, 185 F.3d 1341, 1349 (Fed. Cir. 1999). "When basing the alleged lost profits on lost sales, the patent owner has an initial burden to show a reasonable probability that he would have made the asserted sales 'but for' the infringement. Once the patent owner establishes a reasonable probability of 'but for' causation, 'the burden then shifts to the accused infringer to show that [the patent owner's "but for" causation claim] is unreasonable for some or all of the lost sales." *Id.*
- 63. "To obtain as damages the profits on sales he would have made absent the infringement, *i.e.*, the sales made by the infringer, a patent owner must prove: (1) demand for the patented product, (2) absence of acceptable noninfringing substitutes, (3) his manufacturing and marketing capability to exploit the demand and (4) the amount of profit he would have made." *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978).
- 64. "With such multi-component products, it may often be the case that no one patentee can obtain lost profits on the overall product—the *Panduit* test is a demanding one. A patentee cannot obtain lost profits unless it and only it could have made the sale—there are no non-infringing alternatives or, put differently, the customer would not have purchased the product without the infringing feature." *Mentor Graphics Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1289 (Fed. Cir. 2017). "An award of lost profits may not be speculative. Rather the patent owner must show a reasonable probability that, absent the infringement, it would have made the infringer's sales." *BIC Leisure Prod., Inc. v. Windsurfing Int'l, Inc.*, 1 F.3d 1214, 1218 (Fed. Cir. 1993).
- 65. "[A] fair and accurate reconstruction of the 'but for' market also must take into account, where relevant, alternative actions the infringer foreseeably would have undertaken had

he not infringed," such as offering a non-infringing version of the accused product. *Grain Processing*, 185 F.3d at 1350–51. This analysis is necessary because "[t]he competitor in the 'but for' marketplace is hardly likely to surrender its complete market share when faced with a patent, if it can compete in some other lawful manner." *Id.* at 1351; *see also id.* ("[U]nless the law wishes to systematically overreward patented inventions, it is necessary to inquire about the nature and value of the product that the infringer could have made had he not infringed.") (quoting Schlicher, Patent Law: Legal and Economic Principles § 9.05[2][1] (1997)). An accused infringer need not have an actual working example in order for it to be considered available in the but-for world. *See Grain Processing*, 185 F.3d at 1351 (explaining that "next-best available alternative(s)" need to be considered "regardless of whether the alternative(s) were actually produced and sold during the infringement [period]").

66. The patentee bears the burden to establish all four *Panduit* factors, including proving the "absence of non-infringing alternatives." *Mentor Graphics*, 851 F.3d at 1285. Although the accused infringer has the burden to show that a "substitute was available during the accounting period" if the alleged substitute was not on the market, *Grain Processing*, 185 F.3d at 1353, it remains the patentee's burden to prove the "absence of non-infringing alternatives." *Mentor Graphics*, 851 F.3d at 1285.

D. Reasonable Royalty

- 67. "A patentee receives a reasonable royalty for any of the infringer's sales not included in the lost profit calculation." *Crystal Semiconductor Corp. v. TriTech Microelecs. Int'l, Inc.*, 246 F.3d 1336, 1354 (Fed. Cir. 2001).
- 68. While the patent statute provides a floor of "a reasonable royalty for the use made of the invention by the infringer," 35 U.S.C. § 284, it provides no method for defining a "reasonable" royalty, an exercise that "is not an exact science." *Summit 6, LLC v. Samsung Elecs*.

Co., 802 F.3d 1283, 1296, 1299 (Fed. Cir. 2015). One approach to determining a reasonable royalty is the "hypothetical negotiation approach," which the Federal Circuit has held is a reasonable method. See Summit 6, 802 F.3d at 1299. The hypothetical negotiation approach "attempts to ascertain the royalty upon which the parties would have agreed had they successfully negotiated an agreement just before infringement began." Id. (quoting Lucent Techs., Inc. v. Gateway, Inc., 580 F.3d 1301, 1324 (Fed. Cir. 2009)). The fifteen factors identified in Georgia-Pacific Corp. v. United States Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), are most commonly used for this analysis. The Georgia-Pacific factors are:

- 1. The royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty.
- 2. The rates paid by the licensee for the use of other patents comparable to the patent in suit.
- 3. The nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold.
- 4. The licensor's established policy and marketing program to maintain his patent monopoly by not licensing others to use the invention or by granting licenses under special conditions designed to preserve that monopoly.
- 5. The commercial relationship between the licensor and licensee, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter.
- 6. The effect of selling the patented specialty in promoting sales of other products of the licensee; that existing value of the invention to the licensor as a generator of sales of his non-patented items; and the extent of such derivative or convoyed sales.
- 7. The duration of the patent and the term of the license.
- 8. The established profitability of the product made under the patent; its commercial success; and its current popularity.
- 9. The utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results.
- 10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.

- 11. The extent to which the infringer has made use of the invention; and any evidence probative of the value of that use.
- 12. The portion of the profit or of the selling price that may be customary in the particular business or in comparable businesses to allow for the use of the invention or analogous inventions.
- 13. The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.
- 14. The opinion testimony of qualified experts.
- 15. The amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement.

318 F. Supp. at 1120.

69. Where the accused product includes both an allegedly patented feature and unpatented or conventional features, "damages awarded for patent infringement 'must reflect the value attributable to the infringing features of the product, and no more." CSIRO v. Cisco Sys., Inc., 809 F.3d 1295, 1301 (Fed. Cir. 2015) (quoting Ericsson, Inc. v. D-Link Sys., 773 F. 3d 1201, 1226 (Fed. Cir. 2014)); see also Exmark Mfg. Co., Inc. v. Briggs & Stratton Power Prod. Grp., LLC, 879 F.3d 1332, 1347–48, 350 (Fed. Cir. 2018). "The essential requirement is that the ultimate reasonable royalty award must be based on the incremental value that the patented invention adds to the end product." Exmark Mfg., 879 F.3d at 1348 (quoting Ericsson, 773 F. 3d at 1226). Thus, a patentee must "apportion or separate the damages between the patented improvement and the conventional components of the multicomponent product." Id. Such an apportionment can be applied to the royalty rate or the royalty base, or a combination of both. Id. The apportionment analysis must be based on evidence that is "reliable and tangible, and not conjectural or speculative." LaserDynamics, Inc. v. Quanta Comp., Inc., 694 F.3d 51, 67 (Fed. Cir. 2012) (quoting Garretson v. Clark, 111 U.S. 120, 121 (1884)).

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 107 of 739 PageID #: 12857

Exhibit 5

- "The entire market value rule is a narrow exception to [the] general rule" that "royalties be not based on the entire product, but instead on the 'smallest salable patent-practicing unit." *LaserDynamics*, 694 F.3d at 67. "The entire market value rule allows for the recovery of damages based on the value of an entire apparatus containing several features, when the feature patented constitutes the basis for customer demand." *Id.* Under the entire market value rule, "[i]t is not enough to merely show that the [claimed method] is viewed as valuable, important, or even essential to the use of the [device at issue]. Nor is it enough to show that a [device] without an ODD practicing the [claimed] method would be commercially unviable. Were this sufficient, a plethora of features of a [device at issue] could be deemed to drive demand for the entire product." *Id.* at 68. Further apportionment beyond the smallest salable patent-practicing unit is required "if that unit still contains significant unpatented features." *Virnetx, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1329 (Fed. Cir. 2014).
- 71. "[Q]ualitative testimony that an invention is valuable without being anchored to a quantitative market valuation [is] insufficiently reliable." *CSIRO*, 809 F.3d at 1302. "[T]he district court may reject the extreme figures proffered by the litigants as incredible and substitute an intermediate figure as a matter of its judgment from all of the evidence." *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 926 F.2d 1161, 1168 (Fed. Cir. 1991). Methods to calculate reasonable royalty using licenses must be based on sufficiently comparable licenses. *See CSIRO*, 809 F.3d at 1303–04. "Grounds for exclusion in [the Federal Circuit's] past cases have included, but are not limited to: the license being a litigation settlement agreement, and the patented technology's lack of a relationship to the licensed technology." *Id.* at 1304 n.2 (internal citations omitted). Further, the license comparability analysis must be based on evidence of technological comparability between the licensed technology and the claimed invention. *See*

ResQNet.com, Inc. v. Lansa, Inc., 594 F.3d 860, 871 (Fed. Cir. 2010) ("This trial court, like the one in Lucent, made no effort to link certain licenses to the infringed patent."); Lucent, 580 F.3d at 1329.

E. Prejudgment Interest

Under 35 U.S.C. § 284, upon a finding of infringement, "the court shall award the claimant damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court." 35 U.S.C. § 284 (emphasis added). The prejudgment interest on a damages award "merely serves to make the patent owner whole, since his damages consist not only of the value of the royalty payments but also the foregone use of the money between the time of infringement and the date of the judgment." *Gen. Motors Corp. v. Devex Corp.*, 461 U.S. 648, 656 (1983). The District Court has discretion to determine the applicable rate. *Edwards Lifesciences AG v. CoreValve, Inc.*, No. C.A. 08-91-GMS, 2011 WL 446203, at *13 (D. Del. Feb. 7, 2011), *aff'd in part, remanded in part*, 699 F.3d 1305 (Fed. Cir. 2012).

F. Post-Judgment Interest

73. Post-judgment interest is governed by 28 U.S.C. § 1961. According to 28 U.S.C. § 1961(a):

Interest shall be allowed on any money judgment in a civil case recovered in a district court. Execution therefor may be levied by the marshal, in any case where, by the law of the State in which such court is held, execution may be levied for interest on judgments recovered in the courts of the State. Such interest shall be calculated from the date of the entry of the judgment, at a rate equal to the weekly average 1-year constant maturity Treasury yield, as published by the Board of Governors of the Federal Reserve System, for the calendar week preceding[] the date of the judgment. The Director of the Administrative Office of the United States Courts shall distribute notice of that rate and any changes in it to all Federal judges.

74. The District Court has discretion to determine the applicable rate. *See Edwards Lifesciences AG*, 2011 WL 446203, at *13; *TruePosition Inc. v. Andrew Corp.*, 611 F. Supp. 2d 400, 413 n.15 (D. Del. 2009), *aff'd*, 389 F. App'x 1000 (Fed. Cir. 2010).

G. Permanent Injunctive Relief

75. Under 35 U.S.C. § 283, courts "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." "According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

H. Attorney's Fees and Costs

Natera incorporates by reference as though fully set forth herein its statements of legal authorities set forth *supra* Section II.B.

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 110 of 739 PageID

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

AMERICA HOLDII)	
	Plaintiff,)))	C.A. No. 21-669 (GBW)
V.)	
NATERA, INC.)	
	Defendant.)	
LABORATORY CO AMERICA HOLDI)))	
	Plaintiff,))	C.A. No. 21-1635 (GBW)
v.)	
NATERA, INC.)	
	Defendant.)	

EXHIBIT 6: PLAINTIFF'S WITNESS LIST

Plaintiff Invitae Corporation ("Invitae") identifies the following fact witnesses that it may call live or by deposition at trial. Invitae reserves the right to modify this list in accordance with Fed. R. Civ. P. 26(a)(3), D. Del. LR 16.3, or in view of other events or changed circumstances that may occur before or during trial. Invitae expressly reserves the right to call live or by deposition any witness on its witness list or any witness on the witness list of Defendant. This list is not a commitment that Invitae will call any particular witness at trial, or a representation that any witness listed is available or will appear for trial. If any Invitae, Defendant, or third-party witness is unavailable or refuses to testify live, Invitae reserves the right to use their deposition testimony. With respect to Defendant's witnesses, Invitae reserves the right to introduce testimony through deposition or live examination, as appropriate. In addition, Invitae reserves the right to call any witness, whether listed below or not, to establish authenticity and/or admissibility of any trial exhibit whose authenticity or admissibility is challenged by Defendant. Notwithstanding providing this list, Invitae makes no representation regarding its ability to force any witness to appear at trial unwillingly.

Invitae also reserves the right to call in its case in chief any witness identified by Defendant and to call by deposition any witness identified by Defendant who does not testify at trial or who is unavailable. Invitae also reserves the right to call any witness in its list either in its case in chief, or as a rebuttal witness, or both.

I. INVITAE INTENDS TO CALL THE FOLLOWING WITNESSES AT TRIAL:

- 1. Gregory Porreca (Live)
- 2. Nirav Malani (Live)
- 3. Joshua Earl (Live)
- 4. Dan Krane (Live)

5. Alexander Clemons (Live)

II. INVITAE MAY CALL THE FOLLOWING WITNESSES AT TRIAL:

- 1. Mary Freivogel
- 2. Richard Lusk
- 3. Nirav Malani
- 4. Eric Olivares
- 5. Joshua Paul
- 6. Jim Stuart
- 7. Sajani Swamy
- 6. Andrea Velenich
- 7. Gregory Porreca
- 8. David Bessette
- 9. John Fesko
- 10. Kevin Masukawa
- 11. Solomon Moshkevich
- 12. Raheleh Salari
- 13. Hsin-Ta Wu
- 14. Eric Banks
- 15. Ryan Poplin
- 16. All witnesses named on Natera's trial witness list

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 114 of 739 PageID

EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

C.A. No. 21-cv-669-GBW

C.A. No. 21-cv-1635-GBW

EXHIBIT 7: DEFENDANT'S WITNESS LIST

OF COUNSEL:

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Attorneys for Defendant Natera, Inc.

Exhibit 7

Joshua A. Rosefelt GROOMBRIDGE, WU, BAUGHMAN & STONE LLP 801 17th Street, NW, Suite 1050 Washington, DC 20006 (202) 505-5830 Natera identifies the following fact witnesses that it may call live or by deposition at trial. Natera reserves the right to modify this list in accordance with Fed. R. Civ. P. 26(a)(3), D. Del. L.R. 16.3, or in view of other events or changed circumstances that may occur before or during trial. Natera expressly reserves the right to call live or by deposition any witness on its witness list or any witness on the witness list of Labcorp. This list is not a commitment that Natera will call any particular witness at trial, or a representation that any witness listed is available or will appear for trial. If any Natera, Labcorp, or third-party witness is unavailable or refuses to testify live, Natera reserves the right to use their deposition testimony. With respect to Labcorp's witnesses, Natera reserves the right to introduce testimony through deposition or live examination, as appropriate. In addition, Natera reserves the right to call any witness, whether listed below or not, to establish authenticity and/or admissibility of any trial exhibit whose authenticity or admissibility is challenged by Labcorp. Notwithstanding providing this list, Natera makes no representation regarding its ability to force any witness to appear at trial unwillingly.

Natera also reserves the right to call in its case in chief live or by deposition any witness identified by Labcorp and to call by deposition any witness identified by Labcorp who does not testify at trial or who is unavailable. Natera also reserves the right to call live or by deposition any witness in its list either in its case in chief, or as a rebuttal witness, or both. Natera further reserves the right to amend or supplement this disclosure of witnesses it may call at trial in view of the Court's rulings on any of the parties' objections to the other's witness list.

I. <u>FACT WITNESSES</u>

- 1. Eric Banks (Live)
- 2. John Fesko (Live)
- 3. George Gemelos (Live)
- 4. Solomon Moshkevich (Live)

- 5. Ryan Poplin (Live)
- 6. David Bessette (Deposition)
- 7. Hsin-Ta Wu (Deposition)
- 8. Raheleh Salari (Deposition)
- 9. Mary Freivogel (Deposition)
- 10. Richard Lusk (Deposition)
- 11. Nirav Malani (Deposition)
- 12. Kevin Masukawa (Deposition)
- 13. Hila Moyal (Deposition)
- 14. Eric Olivares (Deposition)
- 15. Joshua Paul (Deposition)
- 16. Gregory Porreca (Deposition)
- 17. Jim Stuart (Deposition)
- 18. Sajani Swamy (Deposition)
- 19. Andrea Velenich (Deposition)
- 20. Plaintiff Labcorp's Corporate Representative(s) (Live or Deposition)
- 21. All witnesses named on Plaintiff Labcorp's Trial Witness List (Pretrial Order, Ex. 6) (Live or Deposition)

II. EXPERT WITNESSES

Natera lists below the names of the expert witnesses it may call at trial. Natera intends to call its expert witnesses live at trial and does not currently intend to seek to introduce their testimony by deposition designation unless one or more of its expert witnesses becomes unavailable and/or is unable or unwilling to travel or testify live at trial.

- 1. Istvan Albert, Ph.D.
- 2. Michael Metzker, Ph.D.

Exhibit 7

3. Nisha Mody, Ph.D.

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 120 of 739 PageID

EXHIBIT 8

Pursuant to D. Del. LR 16.3, Plaintiff Labcorp Corporation of America Holdings ("Plaintiff") hereby submits its list of deposition designations that it may offer at trial.

Plaintiff makes these disclosures without prejudice to amending or supplementing the disclosures in the future if necessary, including but not limited to further reducing the designations set forth below. Plaintiff reserves the right to use any deposition testimony, whether designated or not, for purposes of cross-examination, impeachment, and/or rebuttal. Plaintiff reserves the right to designate additional deposition testimony or call any witness for live testimony in response to any of Natera, Inc.'s ("Defendant") deposition designations or for any other reason. Plaintiff's designations include all exhibits that are referenced in the specified pages and lines, whether or not such exhibits are separately identified. Plaintiff reserves the right to use any deposition testimony designated by Defendant. Inclusion on this list is neither an admission nor a representation as to the admissibility of or relevance to any issue of any deposition designation. By designating deposition testimony, Plaintiff is neither representing nor admitting that Plaintiff has the burden of proof on any topic.

Plaintiff generally objects to any deposition testimony counter-designated by Defendant that is the subject of the parties' stipulations, agreed motions in limine (if any), Plaintiff's motions in limine, motions to exclude certain evidence, Daubert motions and challenges to experts, and any dispositive motions. Plaintiff reserves the right to make additional objections leading up to and at trial.

Plaintiff reserves the right to add to, remove from, and/or supplement these lists of objections to Defendant's counter-designations and Plaintiff's counter-counter designations.

Regarding Plaintiff's objections to Defendant's counter-designations, Plaintiff reserves the right to assert any one, part, or all of its objections. Plaintiff also reserves the right to assert additional objections or counter-counter designations. Plaintiff also reserves the right to assert its original affirmative designation as a counter-counter designation to any counter-designation listed by Defendant.

Pursuant to D. Del. LR 16.3, Defendant Natera, Inc. ("Natera") hereby submits its objections and counter-designations to Invitae's deposition designations.

Defendant makes these objections and disclosures without prejudice to amending or supplementing the objections and disclosures in the future if necessary, including but not limited to reducing the counter-designations set forth in this document, reducing the objections set forth in this document, and/or amending counter-designations in light of Plaintiffs objections and counter-counter-designations. Defendant reserves the right to use any deposition testimony designated by Plaintiff, even if Plaintiff chooses not to use such testimony at trial. Defendant reserves the right to use any deposition testimony, whether designated or not, for purposes of impeachment and/or in rebuttal to any evidence or testimony introduced by Plaintiff. Inclusion on this list is neither an admission nor a representation as to the admissibility of any testimony or exhibits referenced in such testimony.

Defendant generally objects to any deposition testimony designated by Plaintiff that is the subject of the parties' stipulations, agreed motions in limine, Defendant's motions in limine, motions to exclude certain evidence, Daubert motions and challenges to experts, and any dispositive motions. Defendant reserves the right to make additional objections leading up to and at trial.

Defendant's Objection Key

Code	Meaning
402	Not relevant
403	Prejudicial, confusing, and/or waste of time
602	Lack of foundation
701	Opinion testimony by a lay witness
С	Attorney colloquy or objection/not testimony
702/703	Improper foundation/basis for expert testimony
802	Hearsay
NR	Not related
NS	Nonsensical
NQP	No question posed
NA	No answer
I	Incomplete
MIL	Subject of a MIL
V	Vague and ambiguous
HYP	Improper hypothetical
AF	Assumes facts not in evidence
MIS	Mischaracterizes evidence/testimony or is misleading
S	Calls for speculation
Cmpd.	Compound
Scope	Outside the scope of 30(b)(6) designations
NBE	Not best evidence
LC	Calls for legal conclusion
A&A	Asked and answered

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 123 of 739 PageID #: 12873

	Plaintiff's Objection Key
AA	Asked and answered; Fed. R. Evid. 611(a).
ARG	Argumentative, or attorney argument; Fed. R. Evid. 611(a).
BTS	Beyond the scope of examination or of 30(b)(6) topic; Fed R. Evid. 611, Fed. R. Civ. P. 30(b)(6).
BSD	Counter-Designation Beyond the Scope of the Designation(s).
СР	Compound question.
F	No foundation or assumes facts not in evidence; Fed. R. Evid. 602, 703, 901.
FOW	An objection to form is waived if it was not timely made during the deposition, Fed. R. Civ. P. 32(d)(3)(B).
Н	Hearsay if offered for the truth of the matter asserted; Fed. R. Evid. 801, 803, 805.
I	Incomplete designation; Fed. R. Evid. 106, 403.
IH	Incomplete Hypothetical.
L	Leading; Fed. R. Evid. 611(c).
LC	Calls for Legal Conclusion; Fed. R. Evid. 701.
LW	Witness will be testifying live at trial.
MIL	Subjec to motion in limine
MIS	Mischaracterization of testimony or evidence.
NARR	Narrative.
NR	Not responsive; Fed. R. Evid. 611(a).
0	Unqualified Opinion; Calls for improper expert opinion from lay witness; Fed. R. Evid. 701, 702.
ОВ	Attorney Objection improperly designated/Improper designation.
Р	Privileged; Fed. R. Evid. 501, Fed. R. Civ. P. 26(b)(3),(4).
PK	Lack of personal knowledge; Fed. R. Evid. 602.
R	Not relevant; Fed. R. Evid. 401, 402.
SPEC	Calls for Speculation; Fed. R. Evid. 602, 701, 702.
403	Unfairly prejudicial; cumulative, waste of time, Fed. R. Evid. 403.
V	Vague or ambiguous; Fed. R. Evid. 611(a).

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)					
Witness: Banks, Eric					
Date of Desposition: 2023-04-20	Date of Desposition: 2023-04-20				
Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections		
7:11-15	Objections	Designations	Objections		
9:5-12					
9:16-10:3					
10:7-16					
12:23-13:14		13:24-14:19			
16:10-22		16:8-9; 22:22-23:4	BSD		
17:2-18:12		19:14-16; 19:18-20; 20:4-6; 20:9-10; 20:12-20	R, 403		
18:14					
18:16-22	MIS, V	19:14-16; 19:18-20; 20:4-6; 20:9-10; 20:12-20; 21:13-15; 21:23-22:1	R, 403, BSD		
18:24-19:2		19:14-16; 19:18-20; 20:4-6; 20:9-10; 20:12-20; 21:13-15; 21:23-22:1	R, 403, BSD		
19:4-6	MIS, V	19:14-16; 19:18-20; 20:4-6; 20:9-10; 20:12-20; 21:13-15; 21:23-22:1	R, 403, BSD		
19:12	MIS, V	19:14-16; 19:18-20; 20:4-6; 20:9-10; 20:12-20; 21:13-15; 21:23-22:1			
27:13-15	MIS, AF, 602	25:21-26:8; 26:10-14; 26:24- 25; 27:2-4; 189:22-193:2	R, 403, BSD, L, V		
27:17	MIS, AF	25:21-26:8; 26:10-14; 26:24- 25; 27:2-4; 189:22-193:2	R, 403, BSD, L, V		
27:19-28:3	MIS	25:21-26:8; 26:10-14; 26:24- 25; 27:2-4; 189:22-193:2	R, 403, BSD, L, V		
28:5	MIS	25:21-26:8; 26:10-14; 26:24- 25; 27:2-4; ; 189:22-193:2	R, 403, BSD, L, V		
28:8-29:2	MIS	112:20-113:11; 186:2-12; 187:10-188:6	R, 403		
29:4-5	MIS	112:20-113:11; 186:2-12; 187:10-188:6	R, 403		
29:8-11	MIS	112:20-113:11; 186:2-12; 187:10-188:6	R, 403		

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Banks, Eric				
Date of Desposition: 2023-04-20				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
	Objections	Designations	Objections	
29:13-16	MIS	112:20-113:11; 186:2-12;	R, 403	
		187:10-188:6		
29:25-30:2	MIS, V, S			
30:4-5	MIS, V, S			
30:7-9				
30:11				
31:11-32:11	V			
32:13	V			
32:15-33:15		33:23-34:4	R, 403	
34:5-9		34:19-21; 34:23-35:6; 35:19-	R, 403	
		36:1		
36:2-19	MIS, V			
36:21-23				
36:25-37:3		34:19-21; 34:23-35:6; 35:19- 36:1	R, 403	
37:16-24				
38:1				
38:3-8				
39:24-25	V, AF	22:2-8; 38:15-16; 38:18-19; 38:21-39:10; 39:12; 39:14-15; 39:17	R, 403	
40:2	V, AF			
41:20-42:16	602, I, V, S	12:7-9; 12:13-22; 43:4-5; 43:7-11; 46:13-17; 46:21; 50:14-23	R, 403, BSD, PK, SPEC	
42:18-19	602, I, V, S	12:7-9; 12:13-22; 43:4-5; 43:7-11; 46:13-17; 46:21; 50:14-23	R, 403, BSD, PK, SPEC	
42:21-23	602, I, V, S	12:7-9; 12:13-22; 43:4-5; 43:7-11; 46:13-17; 46:21; 50:14-23	R, 403, BSD, PK, SPEC	
42:25-43:2	602, I, V, S	12:7-9; 12:13-22; 43:4-5; 43:7-11; 46:13-17; 46:21; 50:14-23	R, 403, BSD, PK, SPEC	
43:13-14	602, I, V, S	12:7-9; 12:13-22; 43:4-5; 43:7-11; 45:21-22; 45:24- 46:4; 46:13-17; 46:21; 50:14- 23	R, 403, BSD, PK, SPEC, V	

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW) Witness: Banks, Eric Date of Desposition: 2023-04-20								
					Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections
					43:16-44:1	602, I, V, S	12:7-9; 12:13-22; 43:4-5;	R, 403, BSD,
		43:7-11; 45:21-22; 45:24-	PK, SPEC, V					
		46:4; 46:13-17; 46:21; 50:14						
		23						
47:8-48:5		50:6-8						
52:11-13		52:14-16						
53:21-54:6								
54:10-15								
55:15-17	MIS							
55:19-20	MIS							
55:23-56:4								
56:10-12								
56:14-57:9								
57:12-15		57:16-18	BSD					
57:19-22		57:16-18						
57:24-58:10								
58:19-25								
62:6-8								
62:16-63:17								
65:21-22	V, MIS	66:20-25						
65:24-66:1		66:20-25						
66:3-8		66:16-25; 67:9-21						
70:2-19								
71:1-3								
71:5-7								
71:9-11								
71:13-14								
72:15-23								
72:25-73:3								
73:5	V							
73:7-8	V							
73:10-74:2	V							
74:4	V							
74:6-10	V, MIS							
74:12								
74:22-23	V, MIS							
75:25	V, MIS							
75:2-5	V, MIS							
75:7	V, MIS							
75:9-12	V, MIS							

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Banks, Eric				
Date of Desposition: 2023-04-20				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
1 1 0 0	Objections	Designations	Objections	
75:14	V, MIS			
75:16-22	V, MIS			
75:24-25	V, MIS			
76:2-3	V, MIS			
76:5	V, MIS			
76:7-11	V, MIS			
76:17-18	V, MIS			
77:11-17	V, MIS			
77:19-23	V, MIS			
78:17-23		189:22-193:2	R, 403, BSD, L, V	
79:1	I, NQP, V	78:24-25; 80:23-81:1	R, 403	
79:3				
86:10-11		91:25-92:12; 92:15-17;	R, 403, BSD	
		92:19; 96:21-25; 97:2		
86:23		91:25-92:12; 92:15-17;	R, 403, BSD	
		92:19; 96:21-25; 97:2		
86:25-87:1		91:25-92:12; 92:15-17;	R, 403, BSD	
		92:19; 96:21-25; 97:2		
87:4-5		91:25-92:12; 92:15-17;	R, 403, BSD	
		92:19; 96:21-25; 97:2		
87:8-11	V	91:25-92:12; 92:15-17;	R, 403, BSD	
		92:19; 96:21-25; 97:2		
87:13	V	91:25-92:12; 92:15-17;	R, 403, BSD	
		92:19; 96:21-25; 97:2		
87:15-88:1	V	91:25-92:12; 92:15-17;	R, 403, BSD	
		92:19; 96:21-25; 97:2		
88:3-4	V	91:25-92:12; 92:15-17;	R, 403, BSD	
		92:19; 96:21-25; 97:2		
88:6-9		91:25-92:12; 92:15-17;	R, 403, BSD	
		92:19; 96:21-25; 97:2		
88:11-12		91:25-92:12; 92:15-17;	R, 403, BSD	
		92:19; 96:21-25; 97:2		
97:4-6				
97:10				
97:16-18	402, 403, 802			
97:24-98:3	402, 403, 802			
98:8-9	402, 403, 802			
98:11-15	402, 403, 802			
98:23-99:24		100:1-10; 189:22-193:2	BSD	

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)					
Witness: Banks, Eric					
Date of Desposition: 2023-04-20	Date of Desposition: 2023-04-20				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
	Objections	Designations	Objections		
100:11-19	Ι	100:1-10; 112:20-113:11;	R, 403, BSD		
		186:2-12; 187:10-188:6			
100:22-101:10					
101:12-18					
101:22-102:13		102:14-20; 102:25-103:6;	R, 403, BSD, L,		
		103:8; 189:22-193:2	V		
103:10-21		189:22-193:2	R, 403, BSD, L,		
			V		
103:23-104:14	V, MIS	189:22-193:2	R, 403, BSD, L,		
			V		
104:17-21	V, MIS	189:22-193:2	R, 403, BSD, L,		
			V		
104:24-105:5		105:6-8; 189:22-193:2	R, 403, BSD, L,		
			V		
105:9-22		106:12-16; 106:18; 189:22-	R, 403, BSD, L,		
		193:2	V,		
106:20-107:3	V	189:22-193:2	R, 403, BSD, L,		
			V		
107:5		189:22-193:2	R, 403, BSD, L,		
			V		
107:7-11		189:22-193:2	R, 403, BSD, L,		
			V		
107:18-108:4	V	189:22-193:2	R, 403, BSD, L,		
			V		
108:6-8		189:22-193:2	R, 403, BSD, L,		
			V		
108:10-109:4	MIS	109:13-18; 109:20-23;	R, 403, BSD, L,		
		189:22-193:2	V		
109:6-11	MIS	109:13-18; 109:20-23;	R, 403, BSD, L,		
		189:22-193:2	V		
109:25-110:7		109:13-18; 109:20-23;	R, 403, BSD, L,		
1 2 3 3 2 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3		189:22-193:2	V		
110:12-14		111:10-22; 112:2-16	R, 403, BSD		
110:16-20		111:10-22; 112:2-16; 113:12-			
		114:15; 117:5-15; 188:7-	,,		
		189:21			
111:1-7		111:10-22; 112:2-16; 188:7-	R, 403, BSD		
, ,		189:21			
114:16-116:4		113:12-114:15; 188:7-	R, 403		
		189:21	15, 105		
	1	107.41	1		

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Banks, Eric				
Date of Desposition: 2023-04-20				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
	Objections	Designations	Objections	
116:18-20	S	188:7-189:21	R, 403	
116:22		188:7-189:21	R, 403	
116:24-25	NA, I	116:5-14; 117:1-3; 188:7-	R, 403	
		189:21		
117:19-21				
117:23-118:2		118:3-6		
118:7-25				
119:11-12	S			
119:14-17	S			
119:19-22	S			
120:3-5				
120:7-17	MIS; I	120:20-21		
120:23-24				
121:1-10				
121:12-14	V			
121:16	V			
121:18-20	V			
121:22	V			
122:1-2	V			
122:5-123:24	V			
125:15-126:5	MIS, AF			
126:7-11	MIS, AF			
126:13-127:13	Cmpd.			
127:15	•			
128:4-6				
128:15-24				
129:14-16				
129:18-130:3				
130:15-17				
130:22-131:5				
131:15-17				
131:22-132:4				
132:14-16				
133:9-14				
133:23-134:21				
135:10-12				
135:17-136:2				
136:10-12				
136:17-25				
137:24-138:1				

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Banks, Eric				
Date of Desposition: 2023-04-20				
Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections	
138:6-139:1				
139:10-13				
139:18-140:1				
140:10-12				
140:17-21				
140:24-141:17		141:18-20; 142:1-3		
142:7-10				
142:15-20				
143:3-8				
143:13-14				
143:22-144:22		145:10-14		
145:15-146:9		145:10-14		
146:15-18	V, S			
146:20				
147:3-5				
147:7-11		148:4-7		
148:8-22	S	148:4-7		
149:1-3	S			
149:5-13				
149:15				
149:17-20				
150:3-5				
150:16-21	V, S			
150:23				
150:25-151:3		151:4-9		
151:10-152:5		189:22-193:2	R, 403, BSD, L,	
			V	
152:7-153:18	MIS	189:22-193:2	R, 403, BSD, L, V	
153:20	MIS	189:22-193:2	R, 403, BSD, L, V	
153:22-154:16		189:22-193:2	R, 403, BSD, L, V	
154:19-155:7		189:22-193:2	R, 403, BSD, L, V	
155:10-17		189:22-193:2	R, 403, BSD, L, V	
155:19-20		189:22-193:2	R, 403, BSD, L, V	
155:24-25			,	

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW) Witness: Banks, Eric Date of Desposition: 2023-04-20								
					Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections
					156:2-8			
156:25-157:3								
157:9-13								
157:24-158:9								
159:18-160:7		160:8-13						
160:17-18								
160:20-161:3								
161:8-12	S							
161:14	S							
166:1-9								
166:11								
166:13-168:20		168:21-169:16						
169:17-24		168:21-169:16; 169:25- 170:2						
171:7-9		17012						
171:11-172:1		172:2-3; 172:5						
172:7-18		172:19-21						
172:22-23		172:19-21						
172:25		172:19-21						
173:5-6		1/2/19 21						
173:12-174:3								
174:8-9								
174:11-19								
174:22-176:2	V, S							
176:5	V, S							
176:7	V, S							
176:9-177:1								
177:4-9	V, S							
177:11	V, S							
177:13-19		177:20-178:9; 185:15-17; 185:19-22	R, 403, PK					
178:13-15		177:20-178:9; 185:15-17; 185:19-22	R, 403, PK					
178:17-179:15		177:20-178:9; 185:15-17; 185:19-22	R, 403, PK					
179:18-180:2	I	177:20-178:9; 180:6-11; 185:15-17; 185:19-22	R, 403, PK					
180:12-18		177:20-178:9; 185:15-17; 185:19-22	R, 403, PK					

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Banks, Eric				
Date of Desposition: 2023-04-20				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
Labeor p's Opening Designations	Objections	Designations	Objections	
180:21-22		177:20-178:9; 185:15-17;	R, 403, PK	
		185:19-22		
180:24		177:20-178:9; 185:15-17;	R, 403, PK	
		185:19-22		
181:1-182:7	V	177:20-178:9; 185:15-17;	R, 403, PK	
		185:19-22		
182:10-11	V	177:20-178:9; 185:15-17;	R, 403, PK	
		185:19-22		
182:20-183:4		177:20-178:9; 185:15-17;	R, 403, PK	
		185:19-22		
183:7-184:6		177:20-178:9; 185:15-17;	R, 403, PK	
		185:19-22		
184:9-185:5	V	177:20-178:9; 185:15-17;	R, 403, PK	
		185:19-22		
185:7	V	177:20-178:9; 185:15-17;	R, 403, PK	
		185:19-22		
185:9-11	V	177:20-178:9; 185:15-17;	R, 403, PK	
		185:19-22		
185:13	V	177:20-178:9; 185:15-17;	R, 403, PK	
		185:19-22		
193:14-19				

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW) Witness: Bessette, David					
				Date of Desposition: 2023-02-09	Date of Desposition: 2023-02-09
Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections		
5:6-8					
5:11-16					
10:19-24					
11:8-13					
14:12-14	NQP				
14:16-15:4					
15:7-8					
15:10-16:13	402, 403				
17:10-14					
17:18-19					
17:21-18:2	402, 403				
18:5	402, 403				
18:7-13	402, 403				
18:15	402, 403				
18:25-19:14	402, 403				
19:22-24					
20:9-21:11	I, 602, AF, V	21:12-22:8	R		
29:6-11	I, 602, AF, V, S,	26:22-27:21; 27:24-27:24;	R, 403, O, BSD,		
	402, 403	28:2-28:2; 28:5-28:10; 28:21-			
		23; 29:1-4			
29:15-19	I, 602, AF, V, S,	26:22-27:21; 27:24-27:24;	R, 403, O, BSD,		
	402, 403	28:2-28:2; 28:5-28:10; 28:21-	PK, V		
		28:23; 29:1-29:4; 34:14-			
		34:19			
31:4-15	NQP, 602, V,	28:21-23; 29:1-4; 29:22-	R, 403, O, BSD,		
	HYP	29:24; 30:3-30:7; 30:9-	PK, V		
		30:11; 30:14-30:16	,		
31:17-33:4	I, 602, AF, V,	26:22-27:21; 27:24-27:24;	R, 403, O, BSD,		
	HYP	28:2-28:2; 28:5-28:10; 28:21-			
		28:23; 29:1-29:4; 34:14-	,		
		34:19			
33:7-9	I, 602, AF, V	26:22-27:21; 27:24-27:24;	R, 403, O, BSD,		
		28:2-28:2; 28:5-28:10; 28:21-			
		28:23; 29:1-29:4; 34:14-	-, ·		
		34:19			
33:11-14	I, 602, AF, V	26:22-27:21; 27:24-27:24;	R, 403, O, BSD,		
	, , , , , , , , , , , , , , , , , , , ,	28:2-28:2; 28:5-28:10; 28:21-			
		23; 29:1-4	, ·		

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)					
Witness: Bessette, David					
Date of Desposition: 2023-02-09					
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
	Objections	Designations	Objections		
33:16-25	I, 602, AF, V	26:22-27:21; 27:24-27:24;	R, 403, O, BSD,		
		28:2-28:2; 28:5-28:10; 28:21-	PK, V		
		23; 29:1-4			
34:1-3	I, 602, V, HYP, S,	29:22-29:24; 30:3-30:7; 30:9-			
	Scope, PK, 402, 403	30:11; 30:14-30:16	PK, V		
34:6-9	NQP, 602, V,	29:22-29:24; 30:3-30:7; 30:9-	R, 403, O, BSD,		
	HYP, AF, S,	30:11; 30:14-30:16	PK, V		
	Scope, PK, 402,				
	403				
34:11-19	NQP, 602, V,	29:22-29:24; 30:3-30:7; 30:9-	R, 403, O, BSD,		
	HYP, AF, I,	30:11; 30:14-30:16	PK, V		
	Scope, PK, 402,				
	403				
35:5-12	602, I, AF, V, S,	29:22-29:24; 30:3-30:7; 30:9-	R, 403, O, BSD,		
	Scope, PK, 402,	30:11; 30:14-30:16	PK, V		
	403				
35:14-19	NQP, 602, I, AF,	29:22-29:24; 30:3-30:7; 30:9-	R, 403, O, BSD,		
	V, S, Scope, PK,	30:11; 30:14-30:16	PK, V		
	402, 403				
35:23-36:2	NQP, 602, I, AF,	29:22-29:24; 30:3-30:7; 30:9-	R, 403, O, BSD,		
	V, S, Scope, PK,	30:11; 30:14-30:16	PK, V		
	402, 403				
36:4-8	NQP, 602, I, AF,	29:22-29:24; 30:3-30:7; 30:9-			
	V, S, Scope, PK,	30:11; 30:14-30:16;	PK, V		
	402, 403				
36:10-20	NQP, 602, I, AF,	, , , , , , , , , , , , , , , , , , ,	R, 403, O, BSD,		
	V, S, Scope, PK,	29:24; 30:3-30:7; 30:9-	PK, V		
	402, 403	30:11; 30:14-30:16			
36:23	NQP, 602, I, AF,	28:21-28:23; 29:1-4; 29:22-	R, 403, O, BSD,		
	V, S, Scope, PK,	29:24; 30:3-30:7; 30:9-	PK, V		
	402, 403	30:11; 30:14-30:16			
36:25-37:2	602, I, AF, V, S,	28:21-28:23; 29:1-4; 29:22-	R, 403, O, BSD,		
	Scope, PK, 402,	29:24; 30:3-30:7; 30:9-	PK, V		
	403	30:11; 30:14-30:16			
37:4-6	602, I, AF, V, S,	28:21-28:23; 29:1-4; 29:22-	R, 403, O, BSD,		
	Scope, PK, 402,	29:24; 30:3-30:7; 30:9-	PK, V		
	403	30:11; 30:14-30:16			
37:15-22	602, I, V, MIS				

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)					
Witness: Bessette, David					
Date of Desposition: 2023-02-09	Date of Desposition: 2023-02-09				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
1 1 0 0	Objections	Designations	Objections		
38:8-39:19	602, V, I, AF, PK,	26:22-27:21; 27:24-27:24;	R, 403, O, BSD,		
	402, 403, S	28:2-28:2; 28:5-28:10; 28:21-	PK, V		
		23; 29:1-4			
39:21-25	NQP, 602, V, I,	28:21-23; 29:1-4; 29:22-	R, 403, O, BSD,		
	AF	29:24; 30:3-30:7; 30:9-	PK, V		
		30:11; 30:14-30:16			
41:2-11	MIS, I				
42:5-12	Ι	42:13-45:2	R, 403, BSD,		
			PK, O		
45:3	602, I, AF, V,	45:23-45:24; 46:2-46:3; 46:5-	R, 403, NARR		
	Scope	46:6; 46:10-46:21; 47:14-			
		47:19; 48:14-49:1			
45:5-9	602, I, AF, V,	45:23-45:24; 46:2-46:3; 46:5-	R, 403, NARR		
	Scope	46:6; 46:10-46:21; 47:14-			
		47:19; 48:14-49:1			
45:11-22	602, I, AF, V,	45:23-45:24; 46:2-46:3; 46:5-	R, 403, NARR		
	Scope	46:6; 46:10-46:21; 47:14-			
		47:19; 48:14-49:1			
49:2-3	602, I, AF, V,	49:24-50:3; 50:11-50:13;	R, 403, H		
	Scope	50:17-50:23; 52:2-52:3; 52:7-			
		52:25; 53:8-53:10			
49:7-8	602, I, AF, V,	49:24-50:3; 50:11-50:13;	R, 403, H		
	Scope	50:17-50:23; 52:2-52:3; 52:7-			
		52:25; 53:8-53:10			
49:10-17	602, I, AF, V,	49:24-50:3; 50:11-50:13;	R, 403, H		
	Scope	50:17-50:23; 52:2-52:3; 52:7-			
		52:25; 53:8-53:10			
49:20-22	602, I, AF, V,	49:24-50:3; 50:11-50:13;	R, 403, H		
	Scope	50:17-50:23; 52:2-52:3; 52:7-			
		52:25; 53:8-53:10			
53:11-54:1	602, I, 402	58:3-58:6	R		
54:22-55:25	602, I, AF, V, 402	56:7-56:17; 58:7-58:20	R, 403		
56:3-6	602, I, AF, V	56:7-56:17; 58:7-58:20	R, 403		
59:12-21	602, I, AF, V	60:4-60:7	R, BSD		
60:8-61:1	602, I, Scope	58:21-59:8; 63:8-63:13	R, 403, BSD		
61:12-16	602, I, Scope	58:21-59:8; 75:22-76:2	R, 403, BSD, H		
61:21-62:9	602, I, Scope	58:21-59:8	R, 403, BSD		
62:13-24	602, I	58:21-59:8	R, 403, BSD, H		

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW) Witness: Bessette, David				
				Date of Desposition: 2023-02-09
Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections	
70:22-72:10	602, I, AF, V, 402, 403	68:9-68:15; 68:17-68:22; 69:2-69:9; 69:19-69:20; 69:23-69:25; 70:6-70:9; 70:13-70:21; 72:11-72:18; 73:6-73:9; 73:12-73:17; 75:5-75:7	R, 403, BSD, NR	
73:2-5	602, I, AF, V	72:11-72:18; 73:6-73:9; 73:12-73:17; 75:5-75:7	R, 403, H	
76:17-18				
76:22-24				
77:2-17				
77:20-24				
78:2-18				
78:22-24				
83:21-84:19	602, I, AF, V	85:8-12; 85:21-24; 86:1-5; 86:7-13	R, 403	
84:22-85:1	602, I, AF, V	85:8-12; 85:21-24; 86:1-5; 86:7-13	R, 403	
85:3-6	602, I, AF, V,			
	Scope, 402, 403			
87:2-3	602, V, 402, 403			
87:6	602, V, 402, 403			
87:18-21	602, 402, 403			
90:3-22	602, I			
91:1-3	602, I			
91:23-25	602, I			
92:3-6	602, I			
93:7-94:4	602, I, V, C	94:5-94:17	R, 403	
94:18-95:5	602, I,			
95:19-23	602, I, V			
99:12-21	602, I, V	97:17-99:11; 100:6-13; 100:22-102:24	R, 403, BSD, H, O	
103:7-9				
104:11-16	602, I, V, AF, Scope, Cmpd.	105:20-106:1; 106:4-106:11; 106:14-106:16; 106:18-107:19	R, 403, O, BSD, PK	
104:22-105:3	602, I, V, AF, Scope, Cmpd.	105:20-106:1; 106:4-106:11; 106:14-106:16; 106:18-107:19	R, 403, O, BSD, PK	
109:22-23	602, I, 402, 403			

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Bessette, David				
Date of Desposition: 2023-02-09				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
Labcorp's Opening Designations	Objections	Designations	Objections	
109:25-110:2	602, I, 402, 403			
110:5-111:15	602, I, 402, 403			
112:11-113:15	602, I, 402, 403			
113:19-114:1	602, I, 402, 403			
125:14-19	602, I, AF, V, 402,			
	403, Scope			
128:6-21	602, I, AF, V, 402,	128:22-129:2; 129:7-129:16;	R, 403, I, BSD	
	403	129:18-129:24; 130:2-130:4;		
		130:6-130:8; 130:11-14		
130:16-24	402, 403			
131:15-19	602, I, V, 402, 403	131.9-131.13	403	
	002, 1, 1, 102, 103	131.7 131.13	103	
136:1-15	602, I, V, AF,	131:25-132:13; 132:15-	R, 403, I, BSD,	
	MIS	133:24; 134:4-134:16;	NARR	
		134:18-135:25; 136:16-		
		138:3		
138:4-16	602, I, V	138:25-139:3	R	
139:4-8	602, I, V	138:25-139:3	R	
139:17-21	602, I, V	138:25-139:3	R	
139:23-141:4	602, I, V	138:25-139:3	R	
141:6-9	602, I, V	138:25-139:3	R	
141:17-23	602, I, V	138:25-139:3	R	
144:18-25	I, 602, V, AF			
145:1-11	602, V, AF, Scope			
145:14	602, V, AF, Scope			
145:16-21	602, V, AF, Scope			
146:1-7	602, V, AF			
146:9-147:21	602, V, AF			
148:7-149:25	602, V, AF			
150:3-8	602, V, AF			
150:10-12	602, V, AF			
150:14-151:3	602, V, AF			
151:7-17	602, V, AF			
151:20-23	602, V, AF			

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Bessette, David	Witness: Bessette, David			
Date of Desposition: 2023-02-09	T		I	
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
1 1 0 0	Objections	Designations	Objections	
156:7-8	602, V, 403, I	136:16-138:3; 152:9-152:15;		
		152:20-154:14; 155:2-156:6;	NARR, O, H	
		157:1-157:9; 157:13-158:1;		
		158:4-160:19; 160:22-		
		160:23; 161:3-164:3; 164:8-		
		164:9; 164:21-165:13;		
		166:20-167:11; 193:25-		
		194:2; 194:11-194:17		
156:11-13	602, V, 403, I	152:9-152:15; 152:20-	R, 403, BSD,	
		154:14; 155:2-156:6; 157:1-	NARR, O, H	
		157:9; 157:13-158:1; 158:4-		
		160:19; 160:22-160:23;		
		161:3-164:3; 164:8-164:9;		
		164:21-165:13; 166:20-		
		167:11; 193:25-194:2;		
		194:11-194:17		
156:23-25	602, V, 403, I	152:9-152:15; 152:20-	R, 403, BSD,	
150.25 25	002, 1, 103, 1	154:14; 155:2-156:6; 157:1-	NARR, O, H	
		157:9; 157:13-158:1; 158:4-	, , , , , , , , , , , , , , , , , , , ,	
		160:19; 160:22-160:23;		
		161:3-164:3; 164:8-164:9;		
		164:21-165:13; 166:20-		
		167:11; 193:25-194:2;		
		194:11-194:17		
168:6-7	602, I, V, AF			
168:9-18	602, I, V, AF			
168:20-23	602, I, V, AF			
169:1-18	602, I, V, AF			
169:20-22 182:15-23	602, I, V, AF	100.11 100.14. 100.24	D 402 DCD	
102:13-23	602, V, 402, 403,	182:11-182:14; 182:24-	R, 403, BSD	
	I, Scope, PK	182:25; 184:16-184:17; 184:20-185:8		
192.1 22	602 V 402 402		D 402 DCD	
183:1-23	602, V, 402, 403,	182:11-182:14; 182:24- 182:25; 184:16-184:17;	R, 403, BSD	
	I, Scope, PK	184:20-185:8		
		104.20-183.8		

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)			
Witness: Bessette, David			
Date of Desposition: 2023-02-09 Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's
1 1 0 0	Objections	Designations	Objections
184:1-7	602, V, 402, 403,	182:11-182:14; 182:24-	R, 403, BSD
	I, Scope, PK	182:25; 184:16-184:17;	
		184:20-185:8	
185:20-185:25	602, V, 402, 403,	182:11-182:14; 182:24-	R, 403, BSD
	I, Scope, PK	182:25; 184:16-184:17;	
		184:20-185:8	
186:1-3	602, V, 402, 403,	182:11-182:14; 182:24-	R, 403, BSD
	I, Scope, PK	182:25; 184:16-184:17;	
		184:20-185:8	
186:7-17	602, V, 402, 403,	182:11-182:14; 182:24-	R, 403, BSD
	I, Scope, PK	182:25; 184:16-184:17;	
		184:20-185:8	
186:19-20	602, V, 402, 403,	182:11-182:14; 182:24-	R, 403, BSD
	I, Scope, PK	182:25; 184:16-184:17;	
		184:20-185:8	
186:22-24	602, V, 402, 403,	182:11-182:14; 182:24-	R, 403, BSD
	I, Scope, PK	182:25; 184:16-184:17;	
	_	184:20-185:8	
187:2-4	602, V, 402, 403,	182:11-182:14; 182:24-	R, 403, BSD
	I, Scope, PK	182:25; 184:16-184:17;	
	_	184:20-185:8	
187:7-8	602, V, 402, 403,	182:11-182:14; 182:24-	R, 403, BSD
	I, Scope, PK	182:25; 184:16-184:17;	
		184:20-185:8	
188:7-189:8	602, V, 402, 403,		
	I, Scope, PK, S		
191:16-192:8	602, V, I, 402,	192:11-192:20; 193:25-	R, 403, PK, BSD
	403, AF, Scope,	194:2; 194:11-194:17	
	PK	Í	
192:21-193:11	602, V, I, 402,	192:11-192:20; 193:25-	R, 403, PK, BSD
	403, AF, Scope,	194:2; 194:11-194:17	
	PK	,	

Natera, Inc. v. ArcherDX, Inc. (Case No. 1:20-cv-00125-GBW)			
Witness: Fesko, John	, ,	,	
Date of Desposition: 2021-08-20			
T. J. O D	Natera's	Natera's Counter-	Labcorp's
Labcorp's Opening Designations	Objections	Designations	Objections
7:16-20			
8:3-5	I, 602	7:21-8:2	R
65:16-22	I, 602, V, AF	64:12-64:14; 64:17-65:1;	R, 403, BSD,
		65:4-65:5; 65:8-65:14	PK, SPEC
68:23-69:3	I, 602, V, AF, 402,	54:2-54:5; 54:8-54:17; 54:20-	R, 403, BSD,
	403	54:22; 55:24-56:2; 56:5-	PK, SPEC, V, O
		56:18; 56:21-57:11; 57:14-	
		57:20; 57:23-58:1; 64:12-	
		64:14; 64:17-65:1; 65:8-	
		65:14; 66:21-66:25; 67:3-	
		67:17; 69:4-69:7; 69:10-	
		69:14; 69:17; 70:4-70:7;	
		70:10-70:15; 70:24-71:2;	
		71:5-71:7	
69:19-70:3	I, 602, V, AF, 402,	54:2-54:5; 54:8-54:17; 54:20-	R, 403, BSD,
	403	54:22; 55:24-56:2; 56:5-	PK, SPEC, V, O
		56:18; 56:21-57:11; 57:14-	
		57:20; 57:23-58:1; 64:12-	
		64:14; 64:17-65:1; 65:8-	
		65:14; 66:21-66:25; 67:3-	
		67:17; 69:4-69:7; 69:10-	
		69:14; 69:17; 70:4-70:7;	
		70:10-70:15; 70:24-71:2;	
		71:5-71:7	
70:17-18		54:2-54:5; 54:8-54:17; 54:20-	
	403		PK, SPEC, V, O
		56:18; 56:21-57:11; 57:14-	
		57:20; 57:23-58:1; 64:12-	
		64:14; 64:17-65:1; 65:8-	
		65:14; 66:21-66:25; 67:3-	
		67:17; 69:4-69:7; 69:10-	
		69:14; 69:17; 70:4-70:7;	
		70:10-70:15; 70:24-71:2;	
		71:5-71:7	

Natera, Inc. v. ArcherDX, Inc. (Case No. 1:20-cv-00125-GBW)				
Witness: Fesko, John				
Date of Desposition: 2021-08-20				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
Labeor p's Opening Designations	Objections	Designations	Objections	
70:20-23	I, 602, V, AF, 402,	54:2-54:5; 54:8-54:17; 54:20-	R, 403, BSD,	
	403	54:22; 55:24-56:2; 56:5-	PK, SPEC, V, O	
		56:18; 56:21-57:11; 57:14-		
		57:20; 57:23-58:1; 64:12-		
		64:14; 64:17-65:1; 65:8-		
		65:14; 66:21-66:25; 67:3-		
		67:17; 69:4-69:7; 69:10-		
		69:14; 69:17; 70:4-70:7;		
		70:10-70:15; 70:24-71:2;		
		71:5-71:7		
72:4-7	I, 602, V, AF, 402,	54:2-54:5; 54:8-54:17; 54:20-	R, 403, BSD,	
	403	54:22; 55:24-56:2; 56:5-	PK, SPEC, V, O	
		56:18; 56:21-57:11; 57:14-		
		57:20; 57:23-58:1; 64:12-		
		64:14; 64:17-65:1; 65:8-		
		65:14; 66:21-66:25; 67:3-		
		67:17; 69:4-69:7; 69:10-		
		69:14; 69:17; 70:4-70:7;		
		70:10-70:15; 70:24-71:2;		
		71:5-71:7		
72:10	I, 602, V, AF, 402,	54:2-54:5; 54:8-54:17; 54:20-	R, 403, BSD,	
	403	54:22; 55:24-56:2; 56:5-	PK, SPEC, V, O	
		56:18; 56:21-57:11; 57:14-		
		57:20; 57:23-58:1; 64:12-		
		64:14; 64:17-65:1; 65:8-		
		65:14; 66:21-66:25; 67:3-		
		67:17; 69:4-69:7; 69:10-		
		69:14; 69:17; 70:4-70:7;		
		70:10-70:15; 70:24-71:2;		
		71:5-71:7		
76:19-21	I, 602, AF, 403	77:11-77:14; 77:17-77:24	R, 403, PK,	
			SPEC, V	
76:24-77:2	I, 602, AF, 403	77:11-77:14; 77:17-77:24	R, 403, PK,	
			SPEC, V	
77:4-6	I, 602, AF, 403	77:11-77:14; 77:17-77:24	R, 403, PK,	
			SPEC, V	
77:9-10	I, 602, AF, 403	77:11-77:14; 77:17-77:24	R, 403, PK,	
			SPEC, V	
126:3-5	602, 402, 403, AF,			
	MIS			

Witness: Fesko, John Date of Desposition: 2021-08-20	
Data of Dosnosition, 2021 08 20	
Labcorp's Opening Designations Natera's Natera's Counter-	Labcorp's
Objections Designations Objections Designations	Objections
126:8-13 602, 402, 403, AF, MIS	
126:16-19 602, 402, 403, AF,	
MIS	
130:17-131:1 602, 402, 403, I, 128:22-128:24; 129:2-129	:7; R, 403, PK,
AF 131:2-131:4; 131:7-131:2.	5; SPEC, V, O
132:3-132:8; 132:11	
168:8-10 602, 402, 403, I, 169:9-169:11; 169:14-	R, 403, PK,
AF, V 169:18; 171:19-171:24;	SPEC, V
172:2-172:9; 172:12-172:	17;
172:20-172:21	
168:13-169:1 NQP, 602, 402, 169:9-169:11; 169:14-	R, 403, PK,
403, I, AF, V 169:18; 171:19-171:24;	SPEC, V
172:2-172:9; 172:12-172:	17;
172:20-172:21	D 402 DY
169:19-170:22 602, 402, 403, I, 169:9-169:11; 169:14-	R, 403, PK,
AF, V, C, S 169:18; 171:19-171:24; 172:2-172:9; 172:12-172:	SPEC, V
172:29, 172:12-172.	1 /,
170:25-171:12 NQP, 602, 402, 169:9-169:11; 169:14-	R, 403, PK,
403, I, AF, V, S 169:18; 171:19-171:24;	SPEC, V
172:2-172:9; 172:12-172:	· · ·
172:20-172:21	
171:15-18 NQP, 602, 402, 169:9-169:11; 169:14-	R, 403, PK,
403, I, AF, V 169:18; 171:19-171:24;	SPEC, V
172:2-172:9; 172:12-172:	17;
172:20-172:21	
172:23-173:1 602, 402, 403, I, 173:2-173:3; 173:6-174:6;	
AF, V 174:17-174:19; 174:22-	PK, SPEC, V, O,
175:3; 175:5-173:13; 176:	10-CP
17; 177:6-177:7; 178:2- 178:4; 179:5-8	
174:7-8 602, 402, 403, I, 173:2-173:3; 173:6-174:6.	R, 403, BSD,
AF, V 174:17-174:19; 174:22-	PK, SPEC, V, O,
175:3; 175:5-173:13; 176:	
17; 177:6-177:7; 178:2-	
178:4; 179:5-8	

Natera, Inc. v. ArcherDX, Inc. (Case No. 1:20-cv-00125-GBW)					
Witness: Fesko, John	,				
Date of Desposition: 2021-08-20	Date of Desposition: 2021-08-20				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
	Objections	Designations	Objections		
174:11-16	NQP, 602, 402,	173:2-173:3; 173:6-174:6;	R, 403, BSD,		
	403, I, AF, V	174:17-174:19; 174:22-	PK, SPEC, V, O,		
		175:3; 175:5-173:13; 176:10-	CP		
		17; 177:6-177:7; 178:2-			
155 11 10	602 402 402 Y	178:4; 179:5-8	D 402 DCD		
177:11-12	602, 402, 403, I,	173:2-173:3; 173:6-174:6;	R, 403, BSD,		
	AF, V	174:17-174:19; 174:22-	PK, SPEC, V, O,		
		175:3; 175:5-173:13; 176:10-	CP		
		17; 177:6-177:7; 178:2-			
177:15-19	NQP, 602, 402,	178:4; 179:5-8	R, 403, BSD,		
1//:13-19	102, 602, 402, 403, I, AF, V	173:2-173:3; 173:6-174:6; 174:17-174:19; 174:22-	PK, SPEC, V, O,		
	403, 1, AI', V	175:3; 175:5-173:13; 176:10-			
		17; 177:6-177:7; 178:2-	CI		
		178:4; 179:5-8			
177:22-25	602, 402, 403, I,	173:2-173:3; 173:6-174:6;	R, 403, BSD,		
	AF, V		PK, SPEC, V, O,		
	,	175:3; 175:5-173:13; 176:10-			
		17; 177:6-177:7; 178:2-			
		178:4; 179:5-8			
178:5-6	602, 402, 403, I,	173:2-173:3; 173:6-174:6;	R, 403, BSD,		
	AF, V	174:17-174:19; 174:22-	PK, SPEC, V, O,		
		175:3; 175:5-173:13; 176:10-	CP		
		17; 177:6-177:7; 178:2-			
		178:4; 179:5-8			
178:8-14	NQP, 602, 402,	173:2-173:3; 173:6-174:6;	R, 403, BSD,		
	403, I, AF, V	174:17-174:19; 174:22-	PK, SPEC, V, O,		
		175:3; 175:5-173:13; 176:10-	CP		
		17; 177:6-177:7; 178:2-			
170.17 21	NQP, 602, 402,	178:4; 179:5-8	D 402 DCD		
178:17-21	1NQP, 602, 402, 403, I, AF, V	173:2-173:3; 173:6-174:6; 174:17-174:19; 174:22-	R, 403, BSD, PK, SPEC, V, O,		
	403, 1, AI', V	175:3; 175:5-173:13; 176:10-			
		17; 177:6-177:7; 178:2-	CI		
		178:4; 179:5-8			
179:19-22	602, 402, 403, I,	173:2-173:3; 173:6-174:6;	R, 403, BSD,		
	AF, V	174:17-174:19; 174:22-	PK, SPEC, V, O,		
	,	175:3; 175:5-173:13; 176:10-			
		17; 177:6-177:7; 178:2-			
		178:4; 179:5-8			
L		· '			

Natera, Inc. v. ArcherDX, Inc. (Case No. 1:20-cv-00125-GBW)				
Witness: Fesko, John				
Date of Desposition: 2021-08-20				
Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections	
179:25-180:7	NQP, 602, 402, 403, I, AF, V	173:2-173:3; 173:6-174:6; 174:17-174:19; 174:22- 175:3; 175:5-173:13; 176:10- 17; 177:6-177:7; 178:2- 178:4; 179:5-8	R, 403, BSD, PK, SPEC, V, O,	
195:16-18	602, I, 402, 403, I, AF, V	196:18-196:24; 197:2- 197:21	R, 403, BSD, PK, SPEC, V, O, CP	
195:21-25	602, I, 402, 403, I, AF, V	196:18-196:24; 197:2- 197:21	R, 403, BSD, PK, SPEC, V, O, CP	
196:2-4	602, I, 402, 403, I, AF, V	196:18-196:24; 197:2- 197:21	R, 403, BSD, PK, SPEC, V, O, CP	
196:7-17	NQP, 602, I, 402, 403, I, AF, V	196:18-196:24; 197:2- 197:21	R, 403, BSD, PK, SPEC, V, O, CP	

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW) Witness: Fesko, John Date of Desposition: 2023-05-26								
					Labacan's Opening Designations	Natera's	Natera's Counter-	Labcorp's
					Labcorp's Opening Designations	Objections	Designations	Objections
4:4-21	I	9:12-10:9; 10:23-11:9; 14:3-	R, 403, BSD,					
		14:19	PK, SPEC, V					
11:23-12:5	I, 602, 402	10:23-11:9; 14:3-17:4; 17:7-	R, 403, BSD,					
		17:12; 17:15-18:10	PK, SPEC					
12:8-13:19	I, 602, 402	10:23-11:9; 14:3-17:4; 17:7-	R, 403, BSD,					
		17:12; 17:15-18:10	PK, SPEC					
18:14-19	NQP							
18:22-19:12	I, 602	9:12-10:9; 10:23-11:9; 14:3-	R, 403					
		14:15; 29:7-29:16						
19:16-20:14	I, 602, 402	10:23-11:9; 14:3-17:4; 17:7-	R, 403, BSD,					
		17:12; 17:15-18:10; 18:7-10	PK, SPEC					
20:16-21:5	I, 602, 402	10:23-11:9; 14:3-17:4; 17:7-	R, 403, BSD,					
		17:12; 17:15-18:10; 18:7-10	PK, SPEC					
21:17-24:1	I, 602, 402, Scope	10:23-11:9; 14:3-17:4; 17:7-	R, 403, BSD,					
		17:12; 17:15-18:6	PK, SPEC					
24:6-9	I, 602, 402, Scope	10:23-11:9; 14:3-17:4; 17:7-	R, 403, BSD,					
		17:12; 17:15-18:6	PK, SPEC					
27:20-24	I, 602	18:7-10; 26:6-26:16; 26:19-	R					
		27:19						
28:9-29:6	I, 602	18:7-10; 26:6-26:16; 26:19-	R					
		27:19						
31:21-24	NQP							
32:12-15	NQP							
32:22-24	I, 602	18:7-10; 29:12-29:16						
33:2-7	I, 602, AF	18:7-10; 29:12-29:16						
33:11-16	I, 602, AF	18:7-10; 29:12-29:16						
33:19-23	I, 602, AF, LC	18:7-10; 29:12-29:16						
34:1-5	I, 602, AF, V, LC	18:7-10; 29:12-29:16						
34:10-12	I, 602, AF, V, 402	18:7-10; 29:12-29:16						
35:1-11	I, 602, AF, NBE	18:7-10; 29:12-29:16						
36:1-15	I, 602, 402, 403, C	18:7-10; 29:12-29:16						
36:17-20	I, 602, AF, 402,	18:7-10; 29:12-29:16						
	403, C, NBE, V							
37:5	I, 602, AF, 402,	18:7-10; 29:12-29:16						
	403, C, NBE, V							

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW) Witness: Fesko, John					
					Date of Desposition: 2023-05-26
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
	Objections	Designations	Objections		
37:9-38:15	I, 602, AF, V,	4:14-21; 9:12-10:9; 38:25-	R, 403		
	Scope, 402, 403,	39:9			
	PK				
38:20-22	I, 602, AF, V,	4:14-21; 9:12-10:9; 38:25-	R, 403		
	Scope, 402, 403,	39:9			
20.12.16	PK				
39:13-16	602, I, V, NQP	4 1 4 21 0 12 10 0 20 25	D 402		
39:19-41:16	602, I, V, 402,	4:14-21; 9:12-10:9; 38:25-	R, 403		
41.10	403, PK	39:9; 59:19-60:9	D 402		
41:18	602, I, V, 402,	4:14-21; 9:12-10:9; 38:25-	R, 403		
41.22 42.1	403, PK	39:9; 59:19-60:9			
41:22-42:1	NQP, 602	19.7 10. 20.9 14			
42:7-23	602, I, V, AF, LC, NBE, 402, 403,	18:7-10; 30:8-14			
	PK				
43:4	602, I, V, AF, LC,	18:7-10; 30:8-14			
43.4	NBE, 402, 403,	18.7-10, 30.8-14			
	PK				
43:8-46:7	602, I, V, AF, LC,	18.7-10. 30.8-14			
13.0-10.7	Scope, 402, 403,	16.7-10, 50.6-14			
	NBE, PK				
46:20-47:18	602, I, V, AF, LC,	18:7-10; 30:8-14			
10.20 1,7.10	Scope, 402, 403,	10,000			
	NBE, PK				
47:23-24	602, I, V, AF, LC,	18:7-10; 30:8-14			
	Scope, 402, 403,	,			
	NBE, PK				
48:23-49:1	NQP, 602				
49:7-51:6	602, I, V, AF, 402,				
	403, Scope, NBE				
51:12-19	602, I, V, AF, 402,				
	403, Scope				
52:3-14	602, I, V, AF, 402,				
	403, Scope				
52:16-18	602, I, V, AF, 402,				
	403, Scope				
53:9-54:5	602, I, V, 402,				
	403, Scope, AF				

Labcorp Corporation of Amer	rica Holdings v. Na	tera, Inc. (Case No. 1:21-c	v-00669-GBW)
Witness: Fesko, John Date of Desposition: 2023-05-26			
	Natera's	Natera's Counter-	Labcorp's
Labcorp's Opening Designations	Objections	Designations	Objections
54:9-13	602, I, V, 402,		
	403, Scope, AF		
59:19-60:13	602, V, AF		
60:16	602, V, AF		
60:21-61:13	602, V, AF, MIS,		
	402, 403		
61:16-62:17	602, V, AF, MIS,	62:18-62:23	R, 403, PK,
	402, I, 403		SPEC, V
62:24-63:9	602, V, AF, MIS,	62:18-62:23	R, 403, PK,
	402, I, 403		SPEC, V
63:17-64:6	602, V, AF, MIS,	62:18-62:23	R, 403, PK,
	402, I, 403		SPEC, V
64:12-15	602, V, AF, MIS,	62:18-62:23	R, 403, PK,
	402, I, 403		SPEC, V
64:18-66:15	602, V, AF, MIS,	62:18-62:23	R, 403, PK,
	402, I, 403		SPEC, V
66:17-68:15	602, V, AF, MIS,	62:18-62:23	R, 403, PK,
	402, I, 403, Scope		SPEC, V
68:25-69:9	602, V, AF, MIS,	62:18-62:23	R, 403, BSD,
00.25 03.3	402, I, 403, Scope	02.10 02.23	PK, SPEC, V
	102, 1, 103, 200pe		
71:1-9	602, V, AF, MIS,	62:18-62:23; 69:10-23	R, 403, BSD,
	402, I, NQP, 403,		PK, SPEC, V
	Scope		
72:12-:73:3	602, V, AF, MIS,	62:18-62:23; 69:10-23	R, 403, BSD,
72.12 173.6	402, I, 403, Scope	02.10 02.23, 05.10 25	PK, SPEC, V
	102, 1, 103, 200pc		111, 51 20, 1
73:7-13	602, V, AF, MIS,	62:18-62:23; 69:10-23	R, 403, BSD,
, , , , , ,	402, I, Scope, 403	02.10 02.20, 05.110 20	PK, SPEC, V
	.02, 1, 200ps, 100		112, 2123,
73:16-19	602, V, AF, MIS,	62:18-62:23; 69:10-23	R, 403, BSD,
	402, I, 403, Scope		PK, SPEC, V
	, , , , , , , , , , , , , , , , , , ,		
73:22-74:2	602, V, AF, MIS,	62:18-62:23; 69:10-23	R, 403, BSD,
	402, I, 403, Scope	,	PK, SPEC, V
75:21-24	NQP, 602		
76:5-77:25	602, 402		

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW) Witness: Fesko, John Date of Desposition: 2023-05-26 Natera's Natera's Counter-Labcorp's **Labcorp's Opening Designations Objections Designations Objections** 78:4-9 NQP, 602 78:15-19 I, 602, NQP, C, 79:8-25; 82:24-83:6; 115:2-R, 403, BSD, 402, 403 116:6 PK, SPEC, V, O I, 602, PK, 402. 79:20-80:4 79:8-25; 82:24-83:6; 115:2-R, 403, BSD, 403 116:6 PK, SPEC, V, O 79:8-25; 82:24-83:6; 115:2-I, 602, AF 83:4-8 R, 403, BSD, 116:6 PK, SPEC, V, O 79:8-25; 82:24-83:6; 115:2-83:11-12 I, 602, AF R, 403, BSD, 116:6 PK, SPEC, V, O I, 602, AF, NQP R, 403, BSD, 83:14-20 79:8-25; 82:24-83:6; 115:2-PK, SPEC, V, O 116:6 I, 602 R, 403, BSD, 84:8-17 79:8-25; 82:24-83:6; 115:2-PK, SPEC, V, O 116:6 85:10-13 NQP, 602 I, 602, AF, Scope, 85:19-87:9 R, 403, PK, 91:22-92:21 V, 402, 403 **SPEC** 91:22-92:21 87:12-16 R, 403, PK, I, 602, AF, Scope, V, 402, 403 **SPEC** 87:19-22 I, 602, AF, Scope, 91:22-92:21 R, 403, PK, V, 402, 403 **SPEC** 87:25-88:5 I, 602, AF, Scope, 91:22-92:21 R, 403, PK, V, 402, 403 **SPEC** I, 602, AF, Scope, 91:22-92:21 88:12-90:1 R, 403, PK, V, 402, 403 **SPEC** 90:4-5 I, 602, AF, Scope, 91:22-92:21 R, 403, PK, V, 402, 403 **SPEC**

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)					
Witness: Fesko, John					
Date of Desposition: 2023-05-26					
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
90:15-91:12	Objections I, 602, AF, Scope,	Designations 91:22-92:21	Objections R, 403, PK,		
70.13-71.12	V, 402, 403, NBE	71.22-72.21	SPEC		
91:17-21	I, 602, AF, Scope, V, 402, 403, NBE	91:22-92:21	R, 403, PK, SPEC		
96:2-23	I, 602, AF, Scope, V	96:24-97:1			
97:2-4	I, 602, AF, Scope, V	96:24-97:1			
97:7-15	I, 602, AF, Scope, V	96:24-97:1			
98:23-99:2	NQP, 602				
99:8-15	I, 602, AF, 403, NS	100:22-100:25; 103:16- 104:1; 104:5-104:6; 106:12- 106:20; 106:24-107:3; 107:5- 107:13	R, 403, BSD, PK, SPEC		
99:22-25	I, 602, AF, C, 403, NS	100:22-100:25; 103:16- 104:1; 104:5-104:6; 106:12- 106:20; 106:24-107:3; 107:5- 107:13	R, 403, BSD, PK, SPEC		
100:2-21	I, 602, AF, Scope	100:22-100:25; 103:16- 104:1; 104:5-104:6; 106:12- 106:20; 106:24-107:3; 107:5- 107:13	R, 403, BSD, PK, SPEC		
101:1-102:8	I, 602, AF, Scope	100:22-100:25; 103:16- 104:1; 104:5-104:6; 106:12- 106:20; 106:24-107:3; 107:5- 107:13; 109:2-110:15; 116:8- 116:20			
102:11-103:11	I, 602, AF, Scope	100:22-100:25; 103:16- 104:1; 104:5-104:6; 106:12- 106:20; 106:24-107:3; 107:5- 107:13; 109:2-110:15; 116:8- 116:20			

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW) Witness: Fesko, John Date of Desposition: 2023-05-26 Natera's Natera's Counter-Labcorp's **Labcorp's Opening Designations Objections Objections Designations** I, 602, AF, Scope 103:13-15 100:22-100:25; 103:16-R, 403, PK, 104:1; 104:5-104:6; 106:12-SPEC, V 106:20; 106:24-107:3; 107:5-107:13; 116:8-116:20 104:7-105:1 I, 602, AF, Scope 100:22-100:25; 103:16-R, 403, PK, 104:1; 104:5-104:6; 106:12-**SPEC** 106:20; 106:24-107:3; 107:5-107:13 100:22-100:25; 103:16-R, 403, PK, 105:3-106:11 I, 602, AF, Scope 104:1; 104:5-104:6; 106:12-**SPEC** 106:20; 106:24-107:3; 107:5-107:13 I, 602, AF, Scope 100:22-100:25; 103:16-R, 403, PK, 107:14-19 104:1; 104:5-104:6; 106:12-**SPEC** 106:20; 106:24-107:3; 107:5-107:13 100:22-100:25; 103:16-107:22-23 I, 602, AF, Scope R, 403, PK, **SPEC** 104:1; 104:5-104:6; 106:12-106:20; 106:24-107:3; 107:5-107:13 100:22-100:25; 103:16-107:25-108:17 I, 602, AF, Scope R, 403, PK, 104:1; 104:5-104:6; 106:12-**SPEC** 106:20; 106:24-107:3; 107:5-107:13 NQP, 602 108:21-25 I, 602, Scope, V, 110:16-111:4 112:2-112:19 R, 403 AF, 402, 403 111:8-9 112:2-112:19 I, 602, Scope, V, R, 403 AF, 402, 403 I, 602, Scope, V, 112:2-112:19 R, 403 111:12-112:25 AF, 402, 403 113:20-24 I, 602, Scope, V, 4:14-21; 9:12-10:9; 59:19-R, 403, BSD AF, LC, 701, 702, 60:9 703 114:2-3 I, 602, Scope, V, 4:14-21; 9:12-10:9; 59:19-R, 403, BSD AF, LC, 701, 702, 60:9 703

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)					
Witness: Masukawa, Kevin	,				
Date of Desposition: 2023-02-28	1		T		
Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections		
5:24-6:4	NQP				
6:7-10					
9:11-11:1					
11:5-12	Ι				
11:23-13:1	I	13:2-13:8; 13:13-14:12; 14:14-15:3; 15:11-16:10			
21:4-22:14	602, V				
22:21-23:10					
23:13-24:15	602, V, I	26:12-26:14; 26:17-27:17; 18:6-19:5; 162:11-163:25	BSD, R		
24:19-25:5	602, V, I	26:12-26:14; 26:17-27:17; 162:11-163:25	BSD, R		
25:10-26:11	602, V, I	26:12-26:14; 26:17-27:17	N/A		
27:19-20	602, V, I	28:12-29:1; 29:4-29:19; 29:22-30:15	N/A		
27:23-28:1	602, V, I, Cmpd.	28:12-29:1; 29:4-29:19; 29:22-30:15			
28:4-11	602, V, I	28:12-29:1; 29:4-29:19; 29:22-30:15			
30:21-31:1	602, V, I	28:12-29:1; 29:4-29:19; 29:22-30:15			
31:7-32:2	602, V, I	28:12-29:1; 29:4-29:19; 29:22-30:15; 162:11-163:25; 164:2-165:3; 165:6-19	IC, R		
32:17-20	NQP	32:13-16			
32:22-33:10	I, 602	33:11-33:23; 34:2-34:9; 34:12-34:15; 34:21-34:23			
35:3-7	NQP				
35:9-10	I, 602	35:22-36:2; 38:1-41:9; 41:14- 15; 41:17-41:18; 42:4-19; 42:22-43:9; 43:12-14; 44:6- 17; 44:19-22	BSD		
35:12-21	I, 602	35:22-36:2; 38:1-41:9; 41:14- 15; 41:17-41:18; 42:4-19; 42:22-43:9; 43:12-14; 44:6- 17; 44:19-22	BSD		

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)					
Witness: Masukawa, Kevin	,				
Date of Desposition: 2023-02-28		_			
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
1 1 0 0	Objections	Designations	Objections		
36:12-37:25	I, 602, AF, MIS	35:22-36:2; 38:1-41:9; 41:14-			
		15; 41:17-41:18; 42:4-19;			
		42:22-43:9; 43:12-14; 44:6-			
		17; 44:19-22			
49:4-6	I, 602, AF, MIS	38:1-41:9; 41:14-15; 41:17-			
		41:18; 42:4-19; 42:22-43:9;			
		43:12-14; 44:6-17; 44:19-22			
49:9-19	I, 602, AF, MIS	38:1-41:9; 41:14-15; 41:17-			
		41:18; 42:4-19; 42:22-43:9;			
		43:12-14; 44:6-17; 44:19-22			
52:17-25	I, 602, AF, V	50:1-50:12; 50:15-50:18;			
	1, 002, 111,	50:22-51:17; 51:19-51:20;			
		52:3-52:16			
53:3-18	I, 602, AF	50:1-50:12; 50:15-50:18;			
	1, 002, 111	50:22-51:17; 51:19-51:20;			
		52:3-52:16			
55:13-16	I, 602, AF	50:1-50:12; 50:15-50:18;	PK		
	1, 002, 111	50:22-51:17; 51:19-51:20;			
		52:3-52:16; 53:22-54:4; 54:7-			
		55:7; 55:9-12; 56:1-56:9;			
		56:12-56:22; 56:25-57:2;			
		57:24-58:2;			
57:8-15	I, 602, AF	50:1-50:12; 50:15-50:18;	BSD, R, PK,		
	, ,	50:22-51:17; 51:19-51:20;	403, O		
		52:3-52:16; 53:22-54:4; 54:7-	<i>'</i>		
		55:7; 55:9-12; 56:1-56:9;			
		56:12-56:22; 56:25-57:2;			
		57:24-58:2; 143:16-143:23;			
		143:25-144:14; 159:24-			
		161:9; 161:12-162:10			
		,			
57:21-23	I, 602, MIS	56:1-56:9; 56:12-56:22;	BSD, R, PK,		
		56:25-57:2; 57:24-58:2;	403, O		
		143:16-143:23; 143:25-			
		144:14; 159:24-161:9;			
		161:12-162:10			

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW) Witness: Masukawa, Kevin Date of Desposition: 2023-02-28 Natera's Natera's Counter-Labcorp's **Labcorp's Opening Designations Objections Objections Designations** 58:3-7 BSD, R, PK, I, 602 56:1-56:9; 56:12-56:22; 56:25-57:2; 57:24-58:2; 403, O 143:16-143:23; 143:25-144:14; 159:24-161:9; 161:12-162:10 59:9-15 I, 602, Scope **BSD** 59:5-59:8 I, 602, V V. PK 62:14-16 56:1-56:9; 56:12-56:22; 56:25-57:2; 57:24-58:2; 58:8-58:17; 58:20-59:8; 60:4-60:9; 60:12-60:12; 61:5-61:15 62:19-20 I, 602, V 56:1-56:9; 56:12-56:22; V, PK 56:25-57:2; 57:24-58:2 63:5-24 64:4-65:16 65:18-66:17 159:24-160:15; 160:16-602, 402, I BSD, PK 161:9; 161:12-162:10; 164:2-165:3; 165:6-165:19 68:4-7 602, 402, AF, V 69:2-4 I, V 70:7-11 69:23-70:6; 70:12-70:14 70:15-71:13 602, AF, V, I, 69:23-70:6; 70:12-70:14 PK Cmpd. 71:15-72:2 PK 602, AF, V, I 69:23-70:6; 70:12-70:14 72:5-23 602, AF, V, I 69:23-70:6; 70:12-70:14 PK 73:5-17 72:24-72:25; 73:3-73:4; 73:18-74:13; 74:21-75:17 75:18-76:19 602, AF, V, I, S 76:20-77:9; 162:11-163:25; PK 164:2-165:3; 165:6-19 77:10-12 602, AF, V, I, 76:20-77:9; 162:11-163:25; PK Scope, S 164:2-165:3; 165:6-19 602, AF, V, I, 78:2-79:5 77:16-77:17; 77:20-77:20 PK, O Scope, S 79:7-80:13 602, AF, V, I, 77:13-77:17; 77:20-77:20 PK, O Scope, S 80:16-81:22 602, 402, Scope 82:11-83:9 83:15-25 V, S

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)					
Witness: Masukawa, Kevin	Witness: Masukawa, Kevin				
Date of Desposition: 2023-02-28	Date of Desposition: 2023-02-28				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
1 1 0 0	Objections	Designations	Objections		
84:3-85:7	602, 402,				
	403,Scope, I, V				
85:10-86:14	602, 402,				
	403,Scope, I, V				
86:17-87:25	602, 402,				
	403,Scope, I, V, S				
88:21-89:13	MIS, I, Scope, V,	88:1-88:3; 88:7-88:8; 88:14-			
	AF	88:20			
89:16-90:17	MIS, I, Scope, V,	88:1-88:3; 88:7-88:8; 88:14-			
	AF	88:20			
91:4-21	602, I, V, 402	90:18-91:3	PK		
92:1-2	602, V, 402, 403,	92:6-92:9; 92:12-92:18;	PK, O		
	Scope, I	92:21-93:4; 93:7-94:3			
92:5	602, V, 402, 403,				
	Scope, I				
94:4-96:17	602, V, 402, I	92:12-92:18; 92:21-93:4;	BSD, PK		
		93:7-94:3; 96:18-96:20;			
		96:23-99:19			
99:20-100:23	602, V, 402, I	92:12-92:18; 92:21-93:4;	BSD, PK		
		93:7-94:3; 96:18-96:20;			
101.10.21	602 X XX	96:23-99:19	DY/ O		
101:18-21	602, I, V	101:5-17; 101:22-102:9	PK, O		
102:10-103:16	602, I, V, MIS	101:5-17; 101:22-102:9	PK, O		
103:19-104:14	602, I, V, S	101:5-17; 101:22-102:9	PK, O		
105:10-13	I, MIS	106:8-106:15; 159:24-	BSD, R, 403		
		160:15; 160:16-161:9;			
		161:12-162:10; 164:2-165:3;			
105.15.106.7	LMIC	165:6-165:19	DCD D 402		
105:15-106:7	I, MIS	106:8-106:15; 159:24-	BSD, R, 403		
		160:15; 160:16-161:9; 161:12-162:10; 164:2-165:3;			
		,			
108:11-14	NQP	165:6-165:19			
108:16-21	I, AF, 602	109:16-109:21			
109:2-15	1, A1', 002	107.10-107.41			
109:22-110:8					
111:15-24					
112:5-9	NQP				
112:11-113:1	602, I	114:3-6			
114.11-113.1	1002, 1	114.3-0			

Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Masukawa, Kevin				
Date of Desposition: 2023-02-28				
I al a soula On soir a Davier ation a	Natera's	Natera's Counter-	Labcorp's	
Labcorp's Opening Designations	Objections	Designations	Objections	
113:9-114:2	602, I	114:3-6		
116:12-15	NQP			
116:18-117:18	602, I	119:20-120:4		
118:11-15	NQP			
118:23-119:19	602, I, NA	119:20-120:4		
120:5-121:10	602, I	119:20-120:4		
121:15-19	NQP			
121:21-122:14	602, V, AF,			
	Cmpd.			
122:17-19	602, V, AF			
123:15-16	602, I, V	122:20-123:14		
123:21-124:10	602, I, V	122:20-123:14; 124:11-		
		124:23		
124:24-125:2	602, I, A&A	122:20-123:14; 122:20-		
		123:14; 124:11-124:23		
125:5-125:24	602, I, A&A , V	122:20-123:14; 122:20-		
		123:14; 124:11-124:23		
126:2-15	602, I, V	122:20-123:14; 122:20-		
		123:14; 124:11-124:23		
127:7-128:10	602, I, V	124:11-23; 126:16-127:6;	PK	
		128:11-128:19; 129:1-		
		129:13		
128:20-25	602, I	124:11-23; 126:16-127:6;	PK	
		128:11-128:19; 129:1-		
		129:13		
129:19-23	NQP	124:11-23; 126:16-127:6;	PK	
		128:11-128:19; 129:1-		
		129:13		
129:25-130:18	602, S, V			
130:24-131:5	602, S, V, AF	124:11-23; 129:1-13	BSD	
131:9-17	602, S, V, AF,	124:11-23; 129:1-13	BSD	
	MIS			
131:19-20	602, S, V, AF,	124:11-23; 129:1-13	BSD	
	MIS			
131:23-132:3	NQP			
132:5-10	I	133:2-133:18; 134:1-134:4;	BSD	
		134:23-135:6; 135:10-136:3		

148:21-148:25; 149:3- 150:11; 150:14-152:8; 153:12-153:15	Labcorp Corporation of America Holdings v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Labcorp's Opening Designations Natera's Objections Designations Objections 132:16-24	-				
Designations Objections Designations 132:16-24	Date of Desposition: 2023-02-28	1		T	
132:16-24	Labcorp's Opening Designations			_	
134:23-135:6; 135:10-136:3 137:23-138:7	1 1 3 3				
137:23-138:7 NQP 141:4-142:3; 142:6-10 BSD, R, PK	132:16-24	I		BSD	
138:9-21			134:23-135:6; 135:10-136:3		
138:24-139:3 S, 602 141:4-142:3; 142:6-10 BSD, R, PK 139:11-13 141:4-142:3; 142:6-10 BSD, R, PK 139:20-140:15 602, 402 141:4-142:3; 142:6-10 BSD, R, PK 145:19-22 NQP 146:1-147:3 602, I 147:4-148:1; 148:5-148:18; BSD, R, PK 148:21-148:25; 149:3-150:11; 150:14-152:8 BSD, R, PK 148:21-148:25; 149:3-150:11; 150:14-152:8 BSD, R, PK 148:21-148:25; 149:3-150:11; 150:14-152:8 BSD, R, PK 148:21-148:25; 149:3-150:11; 150:14-152:8; I53:12-153:15 153:16-22 602, I, V 147:4-148:1; 148:5-148:18; BSD, R, PK 148:21-148:25; 149:3-150:11; 150:14-152:8; I53:12-153:15 SPEC 154:16-6 602, V, AF Scope, 402 154:10-14 602, V, AF Scope, 402 154:10-14 602, V, AF Scope, 402 154:18-155:11 602, V, AF Scope, 402, S 156:12-157:9 602, I, Scope, 402 157:10-157:17; 159:5-159:15 BSD, PK 157:18-21 602, I, Scope, 402 159:5-159:15 BSD, PK 158:17-159:4 602, I, Scope, 402 159:5-159:15 BSD, PK 158:17-159:4 602, I, Scope, 402 159:5-159:15 BSD, PK 159:16-18 602, I, Scope, 402 I59:5-159:15 BSD, PK 159:16-18 150:16-18 150:16-18 150:16-18 150:16-18 150:16-18 150:16-18 150:16-18 150:16-18 150:16-18 150:16-18 150:16-18 1	137:23-138:7	NQP			
139:11-13	138:9-21		141:4-142:3; 142:6-10	BSD, R, PK	
139:20-140:15	138:24-139:3	S, 602	141:4-142:3; 142:6-10	BSD, R, PK	
145:19-22	139:11-13		141:4-142:3; 142:6-10	BSD, R, PK	
146:1-147:3	139:20-140:15	602, 402	141:4-142:3; 142:6-10	BSD, R, PK	
148:21-148:25; 149:3- 150:11; 150:14-152:8	145:19-22	NQP			
150:11; 150:14-152:8	146:1-147:3	602, I	147:4-148:1; 148:5-148:18;	BSD, R, PK,	
152:9-153:1 602, I 147:4-148:1; 148:5-148:18; BSD, R, PK, SPEC 153:16-22 602, I, V 147:4-148:1; 148:5-148:18; BSD, R, PK, SPEC 153:16-22 602, I, V 147:4-148:1; 148:5-148:18; BSD, R, PK, SPEC 154:1-48:21-148:25; 149:3-150:11; 150:14-152:8; 153:12-153:15 154:1-6 602, V, AF, Scope, 402 154:10-14 602, V, AF, Scope, 402 154:18-155:11 602, V, AF, Scope, 402 155:14-15 602, V, AF, Scope, 402, S 156:12-157:9 602, I, Scope, 402 157:10-157:17; 159:5-159:15 BSD, PK 157:18-21 602, I, Scope, 402, 159:5-159:15 BSD, PK 158:17-159:4 602, I, Scope, 402 159:5-159:15 BSD, PK 159:16-18 602, I, Scope, 402, 159:5-159:15 BSD, PK			148:21-148:25; 149:3-	SPEC	
148:21-148:25; 149:3- 150:11; 150:14-152:8; 153:12-153:15 153:16-22 602, I, V 147:4-148:1; 148:5-148:18; 148:21-148:25; 149:3- 150:11; 150:14-152:8; 153:12-153:15 BSD, R, PK, SPEC 154:1-6 602, V, AF, Scope, 402 154:10-14 602, V, AF, Scope, 402 154:18-155:11 602, V, AF, Scope, 402, S 155:14-15 602, V, AF, Scope, 402, S 156:12-157:9 602, I, Scope, 402, I59:5-159:15 BSD, PK 157:18-21 602, I, Scope, 402, I59:5-159:15 BSD, PK 158:17-159:4 602, I, Scope, 402 159:5-159:15 BSD, PK 159:16-18 BSD, PK			150:11; 150:14-152:8		
148:21-148:25; 149:3- 150:11; 150:14-152:8; 153:12-153:15 153:16-22 602, I, V 147:4-148:1; 148:5-148:18; 148:21-148:25; 149:3- 150:11; 150:14-152:8; 153:12-153:15 BSD, R, PK, SPEC 154:1-6 602, V, AF, Scope, 402 154:10-14 602, V, AF, Scope, 402 154:18-155:11 602, V, AF, Scope, 402, S 155:14-15 602, V, AF, Scope, 402, S 156:12-157:9 602, I, Scope, 402, I59:5-159:15 BSD, PK 157:18-21 602, I, Scope, 402, I59:5-159:15 BSD, PK 158:17-159:4 602, I, Scope, 402 159:5-159:15 BSD, PK 159:16-18 BSD, PK	152:9-153:1	602, I	147:4-148:1; 148:5-148:18;	BSD, R, PK,	
150:11; 150:14-152:8; 153:12-153:15			148:21-148:25; 149:3-	SPEC	
153:12-153:15					
153:16-22 602, I, V 147:4-148:1; 148:5-148:18; BSD, R, PK, 148:21-148:25; 149:3- 150:11; 150:14-152:8; 153:12-153:15 154:1-6 602, V, AF, Scope, 402 154:10-14 602, V, AF, Scope, 402 154:18-155:11 602, V, AF, Scope, 402 155:14-15 602, V, AF, Scope, 402, S 155:14-15 602, V, AF, Scope, 402, S 156:12-157:9 602, I, Scope, 402 157:10-157:17; 159:5- BSD, PK 159:15 157:18-21 602, I, Scope, 402, 159:5-159:15 BSD, PK MIS 157:23-158:2 602, I, Scope, 402, 159:5-159:15 BSD, PK 159:16-18 602, I, Scope, 402, 159:5-159:15 BSD, PK					
148:21-148:25; 149:3- 150:11; 150:14-152:8; 153:12-153:15	153:16-22	602, I, V	147:4-148:1; 148:5-148:18;	BSD, R, PK,	
150:11; 150:14-152:8; 153:12-153:15				SPEC	
153:12-153:15			1		
Scope, 402 154:10-14 602, V, AF, Scope, 402 154:18-155:11 602, V, AF, Scope, 402, S 155:14-15 602, V, AF, Scope, 402, S 156:12-157:9 602, I, Scope, 402 157:10-157:17; 159:5- BSD, PK 157:18-21 602, I, Scope, 402, 159:5-159:15 BSD, PK 157:23-158:2 602, I, Scope, 402, 159:5-159:15 BSD, PK 158:17-159:4 602, I, Scope, 402 159:5-159:15 BSD, PK 159:16-18 602, I, Scope, 402, 159:5-159:15 BSD, PK					
154:10-14 602, V, AF, Scope, 402 154:18-155:11 602, V, AF, Scope, 402, S 155:14-15 602, V, AF, Scope, 402, S 156:12-157:9 602, I, Scope, 402 157:10-157:17; 159:5- BSD, PK 157:18-21 602, I, Scope, 402, 159:5-159:15 BSD, PK 157:23-158:2 602, I, Scope, 402, 159:5-159:15 BSD, PK 158:17-159:4 602, I, Scope, 402 159:5-159:15 BSD, PK 159:16-18 602, I, Scope, 402, 159:5-159:15 BSD, PK	154:1-6	602, V, AF,			
154:10-14 602, V, AF, Scope, 402 154:18-155:11 602, V, AF, Scope, 402, S 155:14-15 602, V, AF, Scope, 402, S 156:12-157:9 602, I, Scope, 402 157:10-157:17; 159:5- BSD, PK 157:18-21 602, I, Scope, 402, 159:5-159:15 BSD, PK 157:23-158:2 602, I, Scope, 402, 159:5-159:15 BSD, PK 158:17-159:4 602, I, Scope, 402 159:5-159:15 BSD, PK 159:16-18 602, I, Scope, 402, 159:5-159:15 BSD, PK					
154:18-155:11 602, V, AF, Scope, 402, S 155:14-15 602, V, AF, Scope, 402, S 157:10-157:17; 159:5- BSD, PK 156:12-157:9 602, I, Scope, 402 157:10-157:17; 159:5- BSD, PK 157:18-21 602, I, Scope, 402, 159:5-159:15 BSD, PK 157:23-158:2 602, I, Scope, 402, 159:5-159:15 BSD, PK 158:17-159:4 602, I, Scope, 402 159:5-159:15 BSD, PK 159:16-18 602, I, Scope, 402, 159:5-159:15 BSD, PK	154:10-14	602, V, AF,			
154:18-155:11 602, V, AF, Scope, 402, S 155:14-15 602, V, AF, Scope, 402, S 157:10-157:17; 159:5- BSD, PK 156:12-157:9 602, I, Scope, 402 157:10-157:17; 159:5- BSD, PK 157:18-21 602, I, Scope, 402, 159:5-159:15 BSD, PK 157:23-158:2 602, I, Scope, 402, 159:5-159:15 BSD, PK 158:17-159:4 602, I, Scope, 402 159:5-159:15 BSD, PK 159:16-18 602, I, Scope, 402, 159:5-159:15 BSD, PK		Scope, 402			
155:14-15 602, V, AF, Scope, 402, S BSD, PK 156:12-157:9 602, I, Scope, 402	154:18-155:11	602, V, AF,			
155:14-15 602, V, AF, Scope, 402, S BSD, PK 156:12-157:9 602, I, Scope, 402		Scope, 402, S			
Scope, 402, S Scope, 402, S 156:12-157:9 602, I, Scope, 402 157:10-157:17; 159:5- BSD, PK 157:18-21 602, I, Scope, 402, 159:5-159:15 BSD, PK MIS MIS BSD, PK 157:23-158:2 602, I, Scope, 402, 159:5-159:15 BSD, PK 158:17-159:4 602, I, Scope, 402, 159:5-159:15 BSD, PK 159:16-18 602, I, Scope, 402, 159:5-159:15 BSD, PK	155:14-15				
159:15 157:18-21 602, I, Scope, 402, 159:5-159:15 MIS 157:23-158:2 602, I, Scope, 402, 159:5-159:15 BSD, PK MIS 158:17-159:4 602, I, Scope, 402 159:5-159:15 BSD, PK 159:16-18 602, I, Scope, 402 159:5-159:15 BSD, PK					
159:15 157:18-21 602, I, Scope, 402, 159:5-159:15 MIS 157:23-158:2 602, I, Scope, 402, 159:5-159:15 BSD, PK MIS 158:17-159:4 602, I, Scope, 402 159:5-159:15 BSD, PK 159:16-18 602, I, Scope, 402 159:5-159:15 BSD, PK	156:12-157:9	1 ' '	157:10-157:17; 159:5-	BSD, PK	
MIS 157:23-158:2 602, I, Scope, 402, 159:5-159:15 MIS 158:17-159:4 602, I, Scope, 402 159:5-159:15 BSD, PK 159:16-18 602, I, Scope, 402, 159:5-159:15 BSD, PK		, , , , ,	· · · · · · · · · · · · · · · · · · ·		
MIS 157:23-158:2 602, I, Scope, 402, 159:5-159:15 MIS 158:17-159:4 602, I, Scope, 402 159:5-159:15 BSD, PK 159:16-18 602, I, Scope, 402, 159:5-159:15 BSD, PK	157:18-21	602, I, Scope, 402.	159:5-159:15	BSD, PK	
157:23-158:2 602, I, Scope, 402, 159:5-159:15 BSD, PK MIS 602, I, Scope, 402 159:5-159:15 BSD, PK 159:16-18 602, I, Scope, 402, 159:5-159:15 BSD, PK		1 1 1			
MIS 158:17-159:4 602, I, Scope, 402 159:5-159:15 BSD, PK 159:16-18 602, I, Scope, 402, 159:5-159:15 BSD, PK	157:23-158:2		159:5-159:15	BSD, PK	
158:17-159:4 602, I, Scope, 402 159:5-159:15 BSD, PK 159:16-18 602, I, Scope, 402, 159:5-159:15 BSD, PK					
	158:17-159:4		159:5-159:15	BSD, PK	
	159:16-18	602, I, Scope. 402	159:5-159:15	BSD, PK	
IMIS, S I I		MIS, S		,	

Natera, Inc. v. ArcherDX, Inc. (Case No. 1:20-cv-00125-GBW)					
Witness: Moshkevich, Solomon					
Date of Desposition: 2021-08-27	Date of Desposition: 2021-08-27				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
	Objections	Designations	Objections		
9:20-24					
11:3-5	I	10:21-11:2			
25:1-2					
25:5	I, 602, 402, AF	22:14-22:15; 22:18-22:18;	BSD, PK		
		22:20-22:20; 22:23-23:3;			
		23:19-24:10			
25:7-26:13	I, 602, 402, AF	22:14-22:15; 22:18-22:18;	BSD, PK		
		22:20-22:20; 22:23-23:3;			
		23:19-24:10			
36:1-9	I, 602, 402, AF, V	35:18-35:19; 35:22-35:24;	BSD, SPEC, PK,		
		36:15-36:15; 36:18-36:25;	403		
		40:7-40:8; 40:11-40:17;			
		40:20-40:24; 41:2-41:11;			
		41:14-41:15			
36:12-13	I, 602, 402, AF, V	35:18-35:19; 35:22-35:24;	BSD, SPEC, PK,		
		36:15-36:15; 36:18-36:25;	403		
		40:7-40:8; 40:11-40:17;			
		40:20-40:24; 41:2-41:11;			
		41:14-41:15			
39:3-4	I, 602, 402, AF, V	35:18-35:19; 35:22-35:24;	BSD, SPEC, PK,		
		36:15-36:15; 36:18-36:25;	403		
		40:7-40:8; 40:11-40:17;			
		40:20-40:24; 41:2-41:11;			
		41:14-41:15			
39:6-18	I, 602, 402, AF, V	35:18-35:19; 35:22-35:24;	BSD, SPEC, PK,		
		36:15-36:15; 36:18-36:25;	403		
		40:7-40:8; 40:11-40:17;			
		40:20-40:24; 41:2-41:11;			
		41:14-41:15			
53:8-10	I, 602, 402	51:4-51:8			
53:13-14	I, 602, 402	51:4-51:8			
53:17	I, 602, 402	51:4-51:8			
58:24-59:2	I, 602, 402, AF	22:14-22:15; 22:18-22:18;	BSD, R, PK		
		22:20-22:20; 22:23-23:3;			
		23:19-24:10			
59:4-5	I, 602, 402, AF	22:14-22:15; 22:18-22:18;	BSD, R, PK		
		22:20-22:20; 22:23-23:3;			
		23:19-24:10			

Natera, Inc. v. ArcherDX, Inc. (Case No. 1:20-cv-00125-GBW)				
Witness: Moshkevich, Solomon				
Date of Desposition: 2021-08-27				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
1 1 0 0	Objections	Designations	Objections	
59:7-10	I, 602, 402, AF	22:14-22:15; 22:18-22:18;	BSD, R, PK	
		22:20-22:20; 22:23-23:3;		
		23:19-24:10		
60:22-24	I, 602, 402, 403,	46:23-47:2; 47:5-47:9;	BSD, R, PK	
	AF, V	47:12; 47:15-47:16; 59:11-		
		59:13; 59:15-60:16; 60:19-		
		60:20; 62:7-63:13; 63:16-		
		64:6; 64:9-11; 68:18-69:7		
61:1-2	I, 602, 402, 403,	46:23-47:2; 47:5-47:9;	BSD, R, PK	
	AF, V	47:12; 47:15-47:16; 59:11-		
		59:13; 59:15-60:16; 60:19-		
		60:20; 62:7-63:13; 63:16-		
		64:6; 64:9-11; 68:18-69:7		
61:4-62:1	I, 602, 402, 403,	46:23-47:2; 47:5-47:9;	BSD, R, PK	
	AF, V	47:12; 47:15-47:16; 59:11-		
		59:13; 59:15-60:16; 60:19-		
		60:20; 62:7-63:13; 63:16-		
		64:6; 64:9-11; 68:18-69:7		
68:1-3	I, 602, 402, 403,	22:14-22:15; 22:18-22:18;	BSD, R, PK	
	AF, V	22:20-22:20; 22:23-23:3;		
		23:19-24:10; 62:7-63:13;		
		63:16-64:6; 64:9-11; 68:18-		
		69:7		
68:14-16	I, 602, 402, 403,	22:14-22:15; 22:18-22:18;	BSD, R, PK	
	AF, V	22:20-22:20; 22:23-23:3;		
		23:19-24:10; 62:7-63:13;		
		63:16-64:6; 64:9-11; 68:18-		
		69:7		
104:4-22	I, 602, 402, AF, V	24:1-24:10; 62:7-63:13;	BSD, R, PK	
		63:16-64:6; 64:9-11		
123:18-20	I, 602, 402, 403,	122:9-122:23; 123:1-123:17;	BSD, R, 403,	
	V, AF	198:25-199:16; 199:22-	PK, SPEC	
		202:4		
123:22-124:6	I, 602, 402, 403,	122:9-122:23; 123:1-123:17;	BSD, R, 403,	
	V, AF	198:25-199:16; 199:22-	PK, SPEC	
		202:4		
124:9-12	I, 602, 402, 403,	122:9-122:23; 123:1-123:17;	BSD, R, 403,	
	V, AF	198:25-199:16; 199:22-	PK, SPEC	
		202:4		

Natera, Inc. v. ArcherDX, Inc. (Case No. 1:20-cv-00125-GBW)				
Witness: Moshkevich, Solomon	Witness: Moshkevich, Solomon			
Date of Desposition: 2021-08-27				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
	Objections	Designations	Objections	
124:15-22	I, 602, 402, 403,	122:9-122:23; 123:1-123:17;		
	V, AF	198:25-199:16; 199:22-	PK, SPEC	
		202:4		
124:24-125:9	I, 602, 402, 403,	122:9-122:23; 123:1-123:17;		
	V, AF	198:25-199:16; 199:22- 202:4	PK, SPEC	
125:11-14	I, 602, 402, 403,	122:9-122:23; 123:1-123:17;	BSD, R, 403,	
	V, AF	198:25-199:16; 199:22-	PK, SPEC	
		202:4	ŕ	
131:9-13	I, 602, 402, 403,	131:14-131:15; 131:17-	BSD, PK, SPEC,	
	V, AF	133:2; 133:15-133:17;	403, H	
		133:23-135:21; 135:23-		
		136:13; 136:16-136:18;		
		136:21-137:9; 137:12-138:7;		
		138:10-138:17; 150:16-		
		150:21		
133:3-4	I, 602, 402, 403,	131:14-131:15; 131:17-	BSD, PK, SPEC,	
	V, AF	133:2; 133:15-133:17;	403, H	
		133:23-135:21; 135:23-		
		136:13; 136:16-136:18;		
		136:21-137:9; 137:12-138:7;		
		138:10-138:17; 150:16- 150:21		
133:7	I, 602, 402, 403,	131:14-131:15; 131:17-	BSD, PK, SPEC,	
133.7	V, AF	133:2; 133:15-133:17;	403, H	
	V, AI	133:23-135:21; 135:23-	403, 11	
		136:13; 136:16-136:18;		
		136:21-137:9; 137:12-138:7;		
		138:10-138:17; 150:16-		
		150:21		
133:9-14	I, 602, 402, 403,	131:14-131:15; 131:17-	BSD, PK, SPEC,	
	V, AF	133:2; 133:15-133:17;	403, H	
		133:23-135:21; 135:23-		
		136:13; 136:16-136:18;		
		136:21-137:9; 137:12-138:7;		
		138:10-138:17; 150:16-		
		150:21		

Natera, Inc. v. ArcherDX, Inc. (Case No. 1:20-cv-00125-GBW)				
Witness: Moshkevich, Solomon	Witness: Moshkevich, Solomon			
Date of Desposition: 2021-08-27				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
1 1 0 0	Objections	Designations	Objections	
150:10-15	I, 602, 402, 403,	131:14-131:15; 131:17-	BSD, PK, SPEC,	
	V, AF	133:2; 133:15-133:17;	403, H	
		133:23-135:21; 135:23-		
		136:13; 136:16-136:18;		
		136:21-137:9; 137:12-138:7;		
		138:10-138:17; 150:16-		
		150:21		
159:5-8	I, 602	159:18-160:1; 198:25-	BSD, R, H	
		199:16; 199:22-202:4		
159:12-17		159:18-160:1; 198:25-	BSD, R, H, PK	
	403	199:16; 199:22-202:4		
160:17-22		160:2-160:4; 160:7-160:16;	BSD, R, H, PK	
161.10	403	161:3-161:13	Dan D 11 D11	
161:1-2		160:2-160:4; 160:7-160:16;	BSD, R, H, PK	
170.11.10	403	161:3-161:13		
179:11-12	NQP, 602, I, 402,	179:18-181:11		
101 12 102 2	403, AF	170 10 101 11 175 10	DCD D I DIV	
181:12-182:2	402, 403, AF	179:18-181:11; 175:18- 176:10; 176:13-176:20;	BSD, R, I, PK, 403	
	402, 403, Ar	176:22-177:10; 177:14-	403	
		177:15; 177:17-177:24;		
		178:2-178:21; 178:24-179:7;		
		179:18-181:11; 182:6-		
		182:12; 182:15-184:1; 185:1-		
		186:10; 186:13-186:14		
		100.10, 100.13 100.14		
184:2-25	602 I V AF 402	179:18-181:11; 175:18-	BSD, R, I, PK,	
10 1.2 25	403	176:10; 176:13-176:20;	403	
		176:22-177:10; 177:14-	103	
		177:15; 177:17-177:24;		
		178:2-178:21; 178:24-179:7;		
		179:18-181:11; 182:6-		
		182:12; 182:15-184:1; 185:1-		
		186:10; 186:13-186:14		
202:5-10	602, I, V, AF, 402,	194:24-195:15; 195:17-	BSD, R, 403,	
	403	195:20; 195:24-196:13;	PK, SPEC	
		195:17-195:20; 196:15;		
		196:18-196:24; 197:2-		
		197:11; 197:14-197:14		

Natera, Inc. v. ArcherDX, Inc. (Case No. 1:20-cv-00125-GBW)				
Witness: Moshkevich, Solomon	Witness: Moshkevich, Solomon			
Date of Desposition: 2021-08-27				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
Labet p's Opening Designations	Objections	Designations	Objections	
202:12-15	NQP, I, V, AF,	194:24-195:15; 195:17-	BSD, R, 403,	
	602, 402, 403	195:20; 195:24-196:13;	PK, SPEC	
		195:17-195:20; 196:15;		
		196:18-196:24; 197:2-		
		197:11; 197:14-197:14		
202:17-20	NQP, I, V, AF,	194:24-195:15; 195:17-	BSD, R, 403,	
	602, 402, 403	195:20; 195:24-196:13;	PK, SPEC	
		195:17-195:20; 196:15;		
		196:18-196:24; 197:2-		
		197:11; 197:14-197:14		
202:23-203:17	I, V, AF, 602, 402,	194:24-195:15; 195:17-	BSD, R, 403,	
	403	195:20; 195:24-196:13;	PK, SPEC	
		195:17-195:20; 196:15;		
		196:18-196:24; 197:2-		
		197:11; 197:14-197:14		
203:20-23	I, V, AF, 602,402,	194:24-195:15; 195:17-	BSD, R, 403,	
	403	195:20; 195:24-196:13;	PK, SPEC	
		195:17-195:20; 196:15;		
		196:18-196:24; 197:2-		
		197:11; 197:14-197:14		
204:22-205:2	I, V, AF, 602, 402,	194:24-195:15; 195:17-	BSD, R, 403,	
	403	195:20; 195:24-196:13;	PK, SPEC	
		195:17-195:20; 196:15;		
		196:18-196:24; 197:2-		
		197:11; 197:14-197:14		
205:4	I, V, AF, 602,	194:24-195:15; 195:17-	BSD, R, 403,	
	NQP, 402, 403	195:20; 195:24-196:13;	PK, SPEC	
		195:17-195:20; 196:15;		
		196:18-196:24; 197:2-		
		197:11; 197:14-197:14		
205:7-16	I, V, AF, 602,	194:24-195:15; 195:17-	BSD, R, 403,	
	NQP, 402, 403	195:20; 195:24-196:13;	PK, SPEC	
		195:17-195:20; 196:15;		
		196:18-196:24; 197:2-		
		197:11; 197:14-197:14		

Natera, Inc. v. ArcherDX, Inc. (Case No. 1:20-cv-00125-GBW)					
Witness: Moshkevich, Solomon					
Date of Desposition: 2021-08-27	Date of Desposition: 2021-08-27				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
	Objections	Designations	Objections		
208:16-20		205:17-207:20; 208:2-4;	BSD, R, 403,		
	403	214:6-217:8; 219:3-219:5;	PK, SPEC, H		
		219:8-219:10; 219:13-			
		219:16; 219:18-219:23;			
		219:25-219:25; 220:3-			
		220:19; 220:25-222:12;			
		222:15-223:6; 223:9-225:24			
208:23-209:14	602, I, V, AF, 402.	205:17-207:20; 208:2-4;	BSD, R, 403,		
	403	214:6-217:8; 219:3-219:5;	PK, SPEC, H		
		219:8-219:10; 219:13-			
		219:16; 219:18-219:23;			
		219:25-219:25; 220:3-			
		220:19; 220:25-222:12;			
		222:15-223:6; 223:9-225:24			
209:17	602. I. V. AF. 402.	205:17-207:20; 208:2-4;	BSD, R, 403,		
	403	214:6-217:8; 219:3-219:5;	PK, SPEC, H		
		219:8-219:10; 219:13-			
		219:16; 219:18-219:23;			
		219:25-219:25; 220:3-			
		220:19; 220:25-222:12;			
		222:15-223:6; 223:9-225:24			
213:12-214:5	602, I, V, AF, 402.	205:17-207:20; 208:2-4;	BSD, R, 403,		
	403	214:6-217:8; 219:3-219:5;	PK, SPEC, H		
		219:8-219:10; 219:13-			
		219:16; 219:18-219:23;			
		219:25-219:25; 220:3-			
		220:19; 220:25-222:12;			
		222:15-223:6; 223:9-225:24			
	1				

Natera, Inc. v. ArcherDX, Inc. (Case No. 1:20-cv-00125-GBW)			
Witness: Moshkevich, Solomon			
Date of Desposition: 2021-08-27			
Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections
217:9-11	602, I, V, AF, 402, 403	205:17-207:20; 208:2-4; 214:6-217:8; 219:3-219:5; 219:8-219:10; 219:13- 219:16; 219:18-219:23; 219:25-219:25; 220:3- 220:19; 220:25-222:12; 222:15-223:6; 223:9-225:24	BSD, R, 403, PK, SPEC, H
217:14-219:2	602, I, V, AF, 402, 403	205:17-207:20; 208:2-4; 214:6-217:8; 219:3-219:5; 219:8-219:10; 219:13- 219:16; 219:18-219:23; 219:25-219:25; 220:3- 220:19; 220:25-222:12; 222:15-223:6; 223:9-225:24	BSD, R, 403, PK, SPEC, H
225:25-226:20	602, I, V, AF, 402, 403	224:14-225:24	R, 403
236:6-7	NQP, I, 602	236:3-236:5; 236:10-236:18	BSD, R, 403
238:20-239:2	602, I, V, AF, 402, 403	226:21-227:16; 236:3-236:5; 236:10-238:16; 240:21- 241:15	BSD, R, 403, I
247:10-11	NQP, I, 602	247:6-247:8; 247:12-247:15; 247:19-247:25; 249:10- 249:19	
248:1-249:9	602, I, V, AF, 402, 403	247:6-247:8; 247:12-247:15; 247:19-247:25; 249:10-249:19	

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
	Witness: Moshkevich, Solomon			
Date of Desposition: 2023-05-23	•	1		
Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections	
6:23-7:1	402			
7:9-11				
13:11-14				
13:20-14:5	Ι	14:6-14:9		
14:20-23				
14:25-15:3	402, 403			
15:5-22	402, S, V, MIS			
15:24-16:17	I	16:19-18:6; 19:17-20:5; 20:16-21:23; 22:2-22:3; 22:10-25:1	BSD, R, 403	
25:3-6				
25:8-10				
25:12-14				
25:16-17				
25:19-22	Scope, I	26:4-27:10		
25:24	Scope, I	26:4-27:10		
26:1-3	Scope			
27:11-13	Scope, I, AF	26:4-27:10; 27:18-27:21; 27:25-28:17; 31:12-31:21; 31:12-31:21; 32:4-32:7; 32:9- 32:15	BSD, PK	
28:18-31:11	Scope, I, AF	26:4-27:10; 27:18-27:21; 27:25-28:17; 31:12-31:21	BSD, PK	
31:24-32:2	Scope, I, AF, S, PK	32:4-32:7; 32:9-32:15	BSD, PK	
32:16-21	Scope, I, AF, S, PK	32:4-32:7; 32:9-32:15;	BSD, PK	
32:23-25	Scope, I, AF, S, PK	32:4-32:7; 32:9-32:15;	BSD, PK	
33:1-21	Scope, I, AF, S, PK	32:4-32:7; 32:9-32:15;	BSD, PK	
33:24	NQP			
34:1-16	LC, Scope			
34:25-36:11	Scope, LC			
37:2-7	Scope, LC, I, AF, S, PK	32:4-32:7; 32:9-32:15; 38:12-38:24; 39:5-39:8; 39:10-39:14		
37:9-10	Scope, LC, I, AF	32:4-32:7; 32:9-32:15; 38:12-38:24; 39:5-39:8; 39:10-39:14	BSD, PK, AA	

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)			
Witness: Moshkevich, Solomon			
Date of Desposition: 2023-05-23	T	T	
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's
	Objections	Designations	Objections
37:12	Scope, LC, I, AF	32:4-32:7; 32:9-32:15; 38:12-	BSD, PK, AA
		38:24; 39:5-39:8; 39:10-	
		39:14	
37:14-15	Scope, LC, I, AF	32:4-32:7; 32:9-32:15; 38:12-	BSD, PK, AA
		38:24; 39:5-39:8; 39:10-	
		39:14	
37:17-20	Scope, LC, I, AF,	32:4-32:7; 32:9-32:15; 38:12-	BSD, PK, AA
	S, HYP, PK	38:24; 39:5-39:8; 39:10-	
		39:14	
37:22	Scope, LC, I, AF,	32:4-32:7; 32:9-32:15; 38:12-	BSD, PK, AA
	S, HYP, PK	38:24; 39:5-39:8; 39:10-	
		39:14	
37:24	Scope, LC, I, AF,	32:4-32:7; 32:9-32:15; 38:12-	BSD, PK, AA
	S, HYP	38:24; 39:5-39:8; 39:10-	
		39:14	
38:1-11	Scope, LC, I, AF,	32:4-32:7; 32:9-32:15; 39:5-	BSD, PK, AA
	S, HYP	39:8; 39:10-39:14	
39:15-20	Scope, LC, I, AF,	32:4-32:7; 32:9-32:15; 39:5-	BSD, PK, AA
	S, HYP	39:8; 39:10-39:14	
40:7-13	Scope, LC, I, AF,	32:4-32:7; 32:9-32:15; 39:5-	BSD, PK, AA
	S, HYP	39:8; 39:10-39:14	
40:17-18	I, V, AF, Scope	41:6-41:17	
40:20-41:1	I, V, AF, Scope	41:6-41:17	
41:18-42:9	I, V, AF, Scope	41:6-41:17	
42:11-43:2	I, V, AF, Scope	41:6-41:17	BSD
43:12-13	I, V, AF, Scope,	41:6-41:17	BSD
	402		
43:15-17	I, V, AF, Scope,	41:6-41:17	BSD
	402		
43:19-20	I, V, AF, Scope,	41:6-41:17	BSD
	402		
43:22	I, V, AF, Scope,	41:6-41:17	BSD
	402		
43:24-44:8	I, V, AF, Scope,	41:6-41:17	BSD
	402		
44:11-21	I, V, AF, Scope,	41:6-41:17	BSD
	402		
44:23-45:25	I, V, AF, Scope,	41:6-41:17	BSD
	402		

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Moshkevich, Solomon	Witness: Moshkevich, Solomon			
Date of Desposition: 2023-05-23			-	
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
Labeor p's Opening Designations	Objections	Designations	Objections	
46:2-48:22	I, V, AF, Scope,	41:6-41:17	BSD	
	402			
50:4	NQP	50:5-8		
50:9-17	Ι			
50:20-51:4	Ι			
51:7-10	Ι			
51:12-15	Ι			
52:5-7	Ι	51:17-52:2	OB	
53:2-11	Ι			
53:14-17	Ι			
53:20-21	Ι			
53:23-54:7	I, 402, 403, MIS			
54:9-11	I, 402, 403, MIS			
55:3-10	Ι			
55:12-17	Ι			
57:9-14	I, V, 402, 403,	60:10-60:18	BSD	
	MIS, Scope			
57:21-25	I, V, 402, 403,	60:10-60:18	BSD	
	MIS, Scope			
58:1-2	I, V, 402, 403,	60:10-60:18	BSD	
	MIS, Scope			
58:12-16	I, V, A&A, 402,	60:10-60:18	BSD	
	403, Scope			
58:18	I, V, 402, 403,	60:10-60:18	BSD	
	MIS, Scope			
58:20-22	I, V, A&A, 402,	60:10-60:18	BSD	
	403, Scope			
58:24	I, V, A&A, 402,	60:10-60:18	BSD	
	403, Scope			
59:1-3	I, V, A&A, 402,	60:10-60:18	BSD	
	403, Scope			
59:5-6	I, V, A&A, 402,	60:10-60:18	BSD	
	403, Scope			
59:8-12	I, V, A&A, 402,	60:10-60:18	BSD	
	403, Scope			
59:14-15	I, V, A&A, 402,	60:10-60:18	BSD	
	403, Scope			
59:19-24	I, V, A&A, 402,	60:10-60:18	BSD	
	403, Scope			

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)			
Witness: Moshkevich, Solomon			
Date of Desposition: 2023-05-23			
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's
Labeor p's Opening Designations	Objections	Designations	Objections
63:5-11	I, V, A&A, 402,	60:10-60:18; 61:25-62:2;	
	403, Scope	64:19-64:23; 64:25-65:4;	
		65:13-66:14	
63:13-17	I, V, A&A, 402,	60:10-60:18; 61:25-62:2;	
	403, Scope	64:19-64:23; 64:25-65:4;	
		65:13-66:14	
63:19-23	I, V, A&A, 402,	60:10-60:18; 61:25-62:2;	
	403, Scope	65:13-66:14	
63:25-64:15	I, V, A&A, AF,	60:10-60:18; 61:25-62:2;	
	MIS, S	65:13-66:14	
64:17-18	I, V, A&A, 402,	60:10-60:18; 61:25-62:2;	
	403, Scope	65:13-66:14	
65:5-11	I, V, A&A, 402,	60:10-60:18; 61:25-62:2;	
	403, Scope	65:13-66:14	
66:16-25	I, V, A&A, 402,	60:10-60:18; 61:25-62:2;	
	403, Scope	65:13-66:14	
67:2-6	I, V, A&A, 402,	60:10-60:18; 61:25-62:2;	
	403, Scope	65:13-66:14	
67:8-9	I	14:6-14:19	BSD
67:11-14	NQP, Scope, PK		
67:19-69:3	602, AF, LC, MIS,	69:6-69:8; 69:10-69:10;	BSD, PK
	I, S, HYP, Scope,	69:12-71:10; 71:18-72:11;	
	PK	72:13-72:17	
69:5	602, AF, LC, MIS,	69:6-69:8; 69:10-69:10;	BSD, PK
	I, S, HY, Scope,	69:12-71:10; 71:18-72:11;	
	PK	72:13-72:17	
71:11-17	602, AF, LC, MIS,	69:6-69:8; 69:10-69:10;	BSD, PK
	I, S, HYP, Scope,	69:12-71:10; 71:18-72:11;	
	PK	72:13-72:17	
72:18-25	602, AF, Scope, S,	31:12-31:21; 32:4-32:7; 32:9-	BSD, PK, I
	HYP, V, PK	32:15; 69:10-69:10; 69:12-	
		71:10; 69:6-69:8; 71:18-	
		72:11; 72:13-72:17	
73:3-11	I, 602, PK	73:1-73:2; 75:3-75:22	BSD, PK, I
73:15-17	I, 602, LC, Scope,	73:1-73:2; 75:3-75:22; 76:7-	BSD, PK
	PK	76:12; 76:14-78:17; 78:19-	
		78:20	
73:19-74:1	I, 602, LC, Scope,	73:1-73:2; 75:3-75:22; 76:7-	BSD, PK
	PK	76:12; 76:14-78:17; 78:19-	
		78:20	

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)					
Witness: Moshkevich, Solomon					
Date of Desposition: 2023-05-23	Date of Desposition: 2023-05-23				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
	Objections	Designations	Objections		
74:9-20	I, 602, LC, Scope,	73:1-73:2; 74:9-11; 74:21-	BSD, PK		
	PK	22; 76:7-76:12; 76:14-78:17;			
		78:19-78:20			
74:23-75:2	I, 602, LC, Scope	73:1-73:2; 74:9-11; 74:21-	BSD, PK		
		22; 76:7-76:12; 76:14-78:17;			
		78:19-78:20			
75:23-76:6	I, 602, LC, Scope,	·	BSD, PK		
	PK	76:12; 76:14-78:17; 78:19-			
		78:20			
78:21	NQP				
78:23-80:1	602, V, PK				
80:8-19	602, I, A&A, 402,	80:21-81:3; 81:24-82:5; 82:7-	BSD, I, PK		
	403	82:7			
81:5-23	602, I, A&A, 402,	80:21-81:3; 81:24-82:5; 82:7-	BSD, I, PK		
	403	82:7			
82:8-12	602, I, LC, Scope,	81:24-82:5; 82:7-82:7	BSD, I, PK		
	402, 403				
82:14-17	602, I, LC, Scope,	81:24-82:5; 82:7-82:7	BSD, I, PK		
	402, 403				
82:19-83:10	602, I, LC, Scope,	81:24-82:5; 82:7-82:7	BSD, I, PK		
	402, 403				
83:12-15		81:24-82:5; 82:7-82:7	BSD, I, PK		
	402, 403				
83:17		81:24-82:5; 82:7-82:7	BSD, I, PK		
	402, 403				
83:19-84:1	602, I, LC, Scope,	81:24-82:5; 82:7-82:7	BSD, I, PK		
	402, 403				
84:22-85:16	602, I, LC, Scope,	81:24-82:5; 82:7-82:7; 84:2-	BSD, I, PK		
	402, 403	84:6; 84:8-84:16; 84:18-			
		84:20			
85:25-86:2	602, I, LC, 402,	85:17-85:19; 85:21-85:21;			
	403, Scope	85:23-85:24			
86:6-8	602, I, LC, 402,	85:17-85:19; 85:21-85:21;	BSD, PK		
	403, Scope	85:23-85:24			
86:10-14	602, I, LC, Scope,	81:24-82:5; 82:7-82:7	BSD, I, PK		
	402, 403				
86:16-17	602, I, LC, Scope,	81:24-82:5; 82:7-82:7	BSD, I, PK		
	402, 403				

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW) Witness: Moshkevich, Solomon			
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's
06.21.07.1	Objections Co2 L L C C	Designations	Objections
86:21-87:1	602, I, LC, Scope,		
	402, 403, S		
87:3-6	602, I, LC, Scope,	81:24-82:5; 82:7-82:7	BSD, I, PK
	402, 403, A&A		
87:8-12	602, I, Scope	88:20-89:17; 89:19-20	BSD, PK
87:14-17	602, I, Scope	88:20-89:17; 89:19-20	BSD, PK
88:4-9	602, I, Scope	88:20-89:17; 89:19-20	BSD, PK
88:11-19	602, I, Scope	88:20-89:17; 89:19-20	BSD, PK
91:24-92:16	602, I	95:2-105:23	BSD, PK
92:19-25	602, I	107:5-108:22; 108:24-109:5	BSD
93:4-10	602, I	107:5-108:22; 108:24-109:5	BSD
93:12-19	602, I	107:5-108:22; 108:24-109:5	BSD
93:21-94:5	602, I, MIS, AF	107:5-108:22; 108:24-109:5	BSD
94:7-8	602, I	107:5-108:22; 108:24-109:5	BSD
94:10-23	602, I	107:5-108:22; 108:24-109:5	BSD
94:25	602, I	107:5-108:22; 108:24-109:5	BSD
109:6-110:16	602, I	105:24-108:22; 108:24- 109:5	BSD
110:20-22	602, I	105:24-108:22; 108:24-	BSD
		109:5	
110:25	602, I	105:24-108:22; 108:24- 109:5	BSD
111:2-19	602, I	105:24-108:22; 108:24- 109:5	BSD
111:21-112:15	602, I	112:17-113:1	
114:4-115:13	602, I, AF	113:2-114:2	
117:7-9	NQP		
117:13	NQP		
117:18-118:10	602, AF, MIS		
118:12-15			
118:17-120:1	I, 602, AF, MIS	120:5-121:4	

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)					
Witness: Moshkevich, Solomon					
Date of Desposition: 2023-05-23	Date of Desposition: 2023-05-23				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
	Objections	Designations	Objections		
121:8	NQP				
121:13-19	I, 602, PK	121:20-123:1			
123:2-11	I, 602	121:20-123:1; 123:25-	BSD, 403		
		130:18; 131:1-131:12			
123:13-24	I, 602	121:20-123:1; 123:25-	BSD, 403		
		130:18; 131:1-131:12			
133:5-8	I, 602, AF, MIS	132:20-133:4; 136:5-136:9;	BSD		
		136:11-136:21; 137:14-			
		138:12; 138:14-139:10			
133:10-12	I, 602, AF, MIS	132:20-133:4; 136:5-136:9;	BSD		
		136:11-136:21; 137:14-			
		138:12; 138:14-139:10			
133:18-134:13	I 602 AE MIC	122.20 122.4. 126.5 126.0.	BSD		
133:18-134:13	I, 602, AF, MIS	132:20-133:4; 136:5-136:9;	BSD		
		136:11-136:21; 137:14-			
		138:12; 138:14-139:10			
134:22-135:2	I, 602, AF, MIS	132:20-133:4; 136:5-136:9;	BSD		
13 1.22 133.2	1, 002, 111 , 11110	136:11-136:21; 137:14-			
		138:12; 138:14-139:10			
		100112, 100111 105110			
135:10-16	I, 602, AF, MIS	132:20-133:4; 136:5-136:9;	BSD		
		136:11-136:21; 137:14-			
		138:12; 138:14-139:10			
135:18-21	I, 602, AF, MIS	132:20-133:4; 136:5-136:9;	BSD		
		136:11-136:21; 137:14-			
		138:12; 138:14-139:10			
125.22 126.4	I CO2 AE MIC	122.20 122.4 126.5 126.0	DCD		
135:23-136:4	I, 602, AF, MIS	132:20-133:4; 136:5-136:9;	BSD		
		136:11-136:21; 137:14-			
		138:12; 138:14-139:10			
136:23-137:10	I, 602, AF, MIS	132:20-133:4; 136:5-136:9;	BSD		
	2, 002, 111, 11110	136:11-136:21; 137:14-			
		138:12; 138:14-139:10			
		150.12, 150.11 157.10			
	1	<u> </u>			

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)			
Witness: Moshkevich, Solomon			
Date of Desposition: 2023-05-23			
Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections
137:12-13	I, 602, AF, MIS	132:20-133:4; 136:5-136:9;	BSD
		136:11-136:21; 137:14-	
		138:12; 138:14-139:10	
140:21-23			
140:25-141:2	Ι	141:13-141:22	BSD, PK
141:4-5	Ι	141:13-141:22	BSD, PK
141:7-12	Ι	141:13-141:22	BSD, PK
141:23-142:2	I		
142:4-143:20	I,S		
143:22-24	S		
144:1-2	S		
144:4			
144:6-145:12	S		
145:22-147:9	602, I		
147:11-148:2			
148:4-5			
148:7-149:23	602, I, MIS, AF		
150:1-16	602, I, MIS, AF		
150:18-152:5	602, I, MIS, AF		
152:7	602, I, MIS, AF		
152:9-16	I, S, NBE, PK	152:17-152:20; 152:25-	BSD
		153:4; 153:6-153:6; 153:18-	
		153:24; 154:1-154:7	
152:22-24	I, S, NBE, PK	152:17-152:20; 152:25-	BSD
		153:4; 153:6-153:6; 153:18-	
		153:24; 154:1-154:7	
153:7-9	I, S, NBE, PK	152:17-152:20; 152:25-	BSD
		153:4; 153:6-153:6; 153:18-	
		153:24; 154:1-154:7	
153:11-17	I, S	152:17-152:20; 152:25-	BSD
		153:4; 153:6-153:6; 153:18-	
		153:24; 154:1-154:7	
154:8-16	602, I, MIS, AF,		
	NBE		
154:18-23	602, I, MIS, AF		

Labcorp Corporation of Ame	rica Holding v. Na	tera, Inc. (Case No. 1:21-cv-	-00669-GBW)
Witness: Moshkevich, Solomon			
Date of Desposition: 2023-05-23			
Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections
154:25-155:2	602, I, MIS, AF		
155:22-156:11	602, I	155:3-155:4; 155:6-155:7	BSD
156:18-22	602, I, MIS, AF		

	of America Holdi	ing v. Natera, Inc. (Case No. 1:21-cv-00669-G	BW)
Witness: Poplin, Ryan Date of Desposition: 2023-04-18			
Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections
9:8-19	С	17:3-9; 18:3-5; 22:25-23:2	
11:8-12			
11:16-18			- 400 - 50-
11:24-13:4		146:6-12; 147:5-7; 147:9-10; 147:12-25; 148:2-7; 148:9-16; 148:18-21; 148:23-149:3; 151:16-21; 151:23-152:1; 152:3	R, 403, BSD, PK, SPEC
13:7-9	Cmpd.	+	
13:11-12			
13:20-22	Cmpd., MIS	13:13-14; 13:16-19	
13:24	Cmpd., MIS	13:13-14; 13:16-19	
13:25-14:1	•		
14:4-14:20			
15:19-25		17:3-9; 18:3-5; 22:25-23:2	R, 403, BSD
18:9-16		17:3-9; 18:3-5; 18:17-23; 19:20-24; 20:4-9; 22:25-23:2; 108:6-109:1; 111:23-14	R, 403, BSD, PK, SPEC, O
19:12-15		18:24-19:4	
22:6-17		22:18-20	
23:14-16		23:17-18	
23:19-24:1		23:17-18; 24:11-17; 26:24-28:7; 28:19-29:8	R, 403, BSD
24:23-25		26:24-28:7; 28:19-29:8; 129:12-130:6; 130:8 21; 130:23-131:7; 131:9-132:1; 132:4-133:7; 133:9-18; 133:20-25; 134:2-8	R, 403, BSD, PK
25:1-12	I	25:24-26:9; 26:11; 26:18-19; 26:21-23; 129:12-130:6; 130:8-21; 130:23-131:7; 131:9-132:1; 132:4-133:7; 133:9-18; 133:20-25; 134:2-8	R, 403, PK
30:9-10	V	30:16-18; 30:20-24; 33:16-34:1	R, 403
30:12-13	V	30:16-18; 30:20-24; 33:16-34:1	R, 403
30:25-31:1	V	30:16-18; 30:20-24; 31:4-12; 31:14-15; 32:3- 24; 33:3-6; 33:16-34:1	R, 403, BSD, PK
31:3	V	30:16-18; 30:20-24; 31:4-12; 31:14-15; 32:3- 24; 33:3-6; 33:16-34:1	R, 403, BSD, PK
35:11-22		33:16-34:1	R, 403, BSD
36:16-37:4		37:5-12	
37:13-15		37:5-12	

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Poplin, Ryan Date of Desposition: 2023-04-18				
37:17-24		37:5-12		
38:17-39:16		37:5-12		
40:11-23		163:8-10; 163:12-15; 165:3-5		
40:25-41:11		163:8-10; 163:12-15; 165:3-5		
41:13-42:1		42:2-14		
43:8-20				
44:2-23	602, V, S			
44:24-45:16	602, V, S			
45:22-23				
45:25-47:15				
48:2-18	MIS			
48:20-25	MIS			
49:2-22	MIS, S			
49:24-50:9	MIS, S			
50:11-17	S			
50:19-25				
51:2				
51:6-21		51:22-52:3		
52:4-24				
53:10-17				
53:24-55:8		53:21-23; 55:19-56:7; 112:15-16; 112:18		

Labcorp Corporation of Witness: Poplin, Ryan	Witness: Poplin, Ryan Date of Desposition: 2023-04-18				
Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections		
57:6-17		121:17-124:3; 124:6-7; 124:9-10; 124:12-15; 124:17-19; 124:21-23; 124:25-125:8; 125:10-12; 125:15-20; 125:22-126:2; 126:4-6; 126:8-9; 126:11-19; 126:21-127:3; 127:5-11; 127:13-20; 134:10-14; 134:16-20; 134:22-24; 135:1-3; 135:5; 135:11-18; 135:20-136:9; 136:11-17; 136:19-25; 137:2-5; 137:8-9; 137:11-13; 137:15-16; 137:18-21; 137:23-138:2; 138:4-6; 138:8-16; 138:18-24; 139:1-4; 139:6; 139:8-12; 139:14-17; 139:19-22; 139:24-140:2; 140:4-9; 140:11-13; 140:15; 140:17-20; 140:22-25; 141:2-6; 141:8-14; 141:16-18; 141:20; 141:22-142:1; 142:3-6; 142:8-13; 142:18-19; 142:21-23; 142:25; 143:3-5; 143:10-16; 143:18-20; 143:23-24; 144:1-5; 144:7-10; 144:12; 145:5-9; 145:11-16; 145:18-23; 145:25-146:3; 146:5; 149:4-23; 149:25-150:6	BSD, PK, SPEOV, NARR, O, L		

Witness: Poplin, Ryan Date of Desposition: 2023-04-18				
Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections	
57:23-58:3		121:17-124:3; 124:6-7; 124:9-10; 124:12-15; 124:17-19; 124:21-23; 124:25-125:8; 125:10-12; 125:15-20; 125:22-126:2; 126:4-6; 126:8-9; 126:11-19; 126:21-127:3; 127:5-11; 127:13-20; ; 134:10-14; 134:16-20; 134:22-24; 135:1-3; 135:5; 135:11-18; 135:20-136:9; 136:11-17; 136:19-25; 137:2-5; 137:8-9; 137:11-13; 137:15-16; 137:18-21; 137:23-138:2; 138:4-6; 138:8-16; 138:18-24; 139:1-4; 139:6; 139:8-12; 139:14-17; 139:19-22; 139:24-140:2; 140:4-9; 140:11-13; 140:15; 140:17-20; 140:22-25; 141:2-6; 141:8-14; 141:16-18; 141:20; 141:22-142:1; 142:3-6; 142:8-13; 142:18-19; 142:21-23; 142:25; 143:3-5; 143:10-16; 143:18-20; 143:23-24; 144:1-5; 144:7-10; 144:12; 145:5-9; 145:11-16; 145:18-23; 145:25-146:3; 146:5; 149:4-23; 149:25-150:6	BSD, PK, SPEC V, NARR, O, L	

Date of Desposition: 2023-04-18 Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections
58:6-60:16		121:17-124:3; 124:6-7; 124:9-10; 124:12-15; 124:17-19; 124:21-23; 124:25-125:8; 125:10-12; 125:15-20; 125:22-126:2; 126:4-6; 126:8-9; 126:11-19; 126:21-127:3; 127:5-11; 127:13-20; ; 134:10-14; 134:16-20; 134:22-24; 135:1-3; 135:5; 135:11-18; 135:20-136:9; 136:11-17; 136:19-25; 137:2-5; 137:8-9; 137:11-13; 137:15-16; 137:18-21; 137:23-138:2; 138:4-6; 138:8-16; 138:18-24; 139:1-4; 139:6; 139:8-12; 139:14-17; 139:19-22; 139:24-140:2; 140:4-9; 140:11-13; 140:15; 140:17-20; 140:22-25; 141:2-6; 141:8-14; 141:16-18; 141:20; 141:22-142:1; 142:3-6; 142:8-13; 142:18-19; 142:21-23; 142:25; 143:3-5; 143:10-16; 143:18-20; 143:23-24; 144:1-5; 144:7-10; 144:12; 145:5-9; 145:11-16; 145:18-23; 145:25-146:3; 146:5; 149:4-23; 149:25-150:6	R, 403, BTS, BSD, PK, SPEC V, NARR, O, L

Date of Desposition: 2023-04-18 Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections
61:7-62:5		121:17-124:3; 124:6-7; 124:9-10; 124:12-15; 124:17-19; 124:21-23; 124:25-125:8; 125:10-12; 125:15-20; 125:22-126:2; 126:4-6; 126:8-9; 126:11-19; 126:21-127:3; 127:5-11; 127:13-20; ; 134:10-14; 134:16-20; 134:22-24; 135:1-3; 135:5; 135:11-18; 135:20-136:9; 136:11-17; 136:19-25; 137:2-5; 137:8-9; 137:11-13; 137:15-16; 137:18-21; 137:23-138:2; 138:4-6; 138:8-16; 138:18-24; 139:1-4; 139:6; 139:8-12; 139:14-17; 139:19-22; 139:24-140:2; 140:4-9; 140:11-13; 140:15; 140:17-20; 140:22-25; 141:2-6; 141:8-14; 141:16-18; 141:20; 141:22-142:1; 142:3-6; 142:8-13; 142:18-19; 142:21-23; 142:25; 143:3-5; 143:10-16; 143:18-20; 143:23-24; 144:1-5; 144:7-10; 144:12; 145:5-9; 145:11-16; 145:18-23; 145:25-146:3; 146:5; 149:4-23; 149:25-150:6	R, 403, BTS, BSD, PK, SPEC V, NARR, O, L

Witness: Poplin, Ryan Date of Desposition: 2023-04-18				
Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections	
63:17-64:8	MIS	121:17-124:3; 124:6-7; 124:9-10; 124:12-15; 124:17-19; 124:21-23; 124:25-125:8; 125:10-12; 125:15-20; 125:22-126:2; 126:4-6; 126:8-9; 126:11-19; 126:21-127:3; 127:5-11; 127:13-20; ; 134:10-14; 134:16-20; 134:22-24; 135:1-3; 135:5; 135:11-18; 135:20-136:9; 136:11-17; 136:19-25; 137:2-5; 137:8-9; 137:11-13; 137:15-16; 137:18-21; 137:23-138:2; 138:4-6; 138:8-16; 138:18-24; 139:1-4; 139:6; 139:8-12; 139:14-17; 139:19-22; 139:24-140:2; 140:4-9; 140:11-13; 140:15; 140:17-20; 140:22-25; 141:2-6; 141:8-14; 141:16-18; 141:20; 141:22-142:1; 142:3-6; 142:8-13; 142:18-19; 142:21-23; 142:25; 143:3-5; 143:10-16; 143:18-20; 143:23-24; 144:1-5; 144:7-10; 144:12; 145:5-9; 145:11-16; 145:18-23; 145:25-146:3; 146:5; 149:4-23; 149:25-150:6	BSD, PK, SPEOV, NARR, O, L	

Date of Desposition: 2023-04-18 Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections
64:10-16		121:17-124:3; 124:6-7; 124:9-10; 124:12-15; 124:17-19; 124:21-23; 124:25-125:8; 125:10-12; 125:15-20; 125:22-126:2; 126:4-6; 126:8-9; 126:11-19; 126:21-127:3; 127:5-11; 127:13-20; ; 134:10-14; 134:16-20; 134:22-24; 135:1-3; 135:5; 135:11-18; 135:20-136:9; 136:11-17; 136:19-25; 137:2-5; 137:8-9; 137:11-13; 137:15-16; 137:18-21; 137:23-138:2; 138:4-6; 138:8-16; 138:18-24; 139:1-4; 139:6; 139:8-12; 139:14-17; 139:19-22; 139:24-140:2; 140:4-9; 140:11-13; 140:15; 140:17-20; 140:22-25; 141:2-6; 141:8-14; 141:16-18; 141:20; 141:22-142:1; 142:3-6; 142:8-13; 142:18-19; 142:21-23; 142:25; 143:3-5; 143:10-16; 143:18-20; 143:23-24; 144:1-5; 144:7-10; 144:12; 145:5-9; 145:11-16; 145:18-23; 145:25-146:3; 146:5; 149:4-23; 149:25-150:6	R, 403, BTS, BSD, PK, SPEC V, NARR, O, L

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW) Witness: Poplin, Ryan				
Date of Desposition: 2023-04-18 Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections	
64:20-22		124:6-7; 124:9-10; 124:12-15; 124:17-19; 124:21-23; 124:25-125:8; 125:10-12; 125:15-20; 125:22-126:2; 126:4-6; 126:8-9; 126:11-19; 126:21-127:3; 127:5-11; 127:13-20; 127:21-129:9; ; 134:10-14; 134:16-20; 134:22-24; 135:1-3; 135:5; 135:11-18; 135:20-136:9; 136:11-17; 136:19-25; 137:2-5; 137:8-9; 137:11-13; 137:15-16; 137:18-21; 137:23-138:2; 138:4-6; 138:8-16; 138:18-24; 139:1-4; 139:6; 139:8-12; 139:14-17; 139:19-22; 139:24-140:2; 140:4-9; 140:11-13; 140:15; 140:17-20; 140:22-25; 141:2-6; 141:8-14; 141:16-18; 141:20; 141:22-142:1; 142:3-6; 142:8-13; 142:18-19; 142:21-23; 142:25; 143:3-5; 143:10-16; 143:18-20; 143:23-24; 144:1-5; 144:7-10; 144:12; 145:5-9; 145:11-16; 145:18-23; 145:25-146:3; 146:5	V, NARR, O, L	

Witness: Poplin, Ryan Date of Desposition: 2023-04-18				
Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections	
65:6-11		65:12-67:1; 67:8-68:3; 124:6-7; 124:9-10; 124:12-15; 124:17-19; 124:21-23; 124:25-125:8; 125:10-12; 125:15-20; 125:22-126:2; 126:4-6; 126:8-9; 126:11-19; 126:21-127:3; 127:5-11; 127:13-20; 127:21-129:9; ; 134:10-14; 134:16-20; 134:22-24; 135:1-3; 135:5; 135:11-18; 135:20-136:9; 136:11-17; 136:19-25; 137:2-5; 137:8-9; 137:11-13; 137:15-16; 137:18-21; 137:23-138:2; 138:4-6; 138:8-16; 138:18-24; 139:1-4; 139:6; 139:8-12; 139:14-17; 139:19-22; 139:24-140:2; 140:4-9; 140:11-13; 140:15; 140:17-20; 140:22-25; 141:2-6; 141:8-14; 141:16-18; 141:20; 141:22-142:1; 142:3-6; 142:8-13; 142:18-19; 142:21-23; 142:25; 143:3-5; 143:10-16; 143:18-20; 143:23-24; 144:1-5; 144:7-10; 144:12; 145:5-9; 145:11-16; 145:18-23; 145:25-146:3; 146:5		

Witness: Poplin, Ryan Date of Desposition: 2023-04-18				
Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections	
69:6-16		69:17-23; 124:6-7; 124:9-10; 124:12-15; 124:17-19; 124:21-23; 124:25-125:8; 125:10-12; 125:15-20; 125:22-126:2; 126:4-6; 126:8-9; 126:11-19; 126:21-127:3; 127:5-11; 127:13-20; 127:21-129:9; ; 134:10-14; 134:16-20; 134:22-24; 135:1-3; 135:5; 135:11-18; 135:20-136:9; 136:11-17; 136:19-25; 137:2-5; 137:8-9; 137:11-13; 137:15-16; 137:18-21; 137:23-138:2; 138:4-6; 138:8-16; 138:18-24; 139:1-4; 139:6; 139:8-12; 139:14-17; 139:19-22; 139:24-140:2; 140:4-9; 140:11-13; 140:15; 140:17-20; 140:22-25; 141:2-6; 141:8-14; 141:16-18; 141:20; 141:22-142:1; 142:3-6; 142:8-13; 142:18-19; 142:21-23; 142:25; 143:3-5; 143:10-16; 143:18-20; 143:23-24; 144:1-5; 144:7-10; 144:12; 145:5-9; 145:11-16; 145:18-23; 145:25-146:3; 146:5	V, NARR, O, L	

Witness: Poplin, Ryan		ing v. Natera, Inc. (Case No. 1:21-cv-00669-G	,	
Date of Desposition: 2023-04-18				
Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections	
70:3-14		124:6-7; 124:9-10; 124:12-15; 124:17-19;	R, 403, BTS,	
		124:21-23; 124:25-125:8; 125:10-12; 125:15-	BSD, PK, SPEC	
		20; 125:22-126:2; 126:4-6; 126:8-9; 126:11-	V, NARR, O, L	
		19; 126:21-127:3; 127:5-11; 127:13-20;		
		127:21-129:9; ; 134:10-14; 134:16-20;		
		134:22-24; 135:1-3; 135:5; 135:11-18;		
		135:20-136:9; 136:11-17; 136:19-25; 137:2-		
		5; 137:8-9; 137:11-13; 137:15-16; 137:18-		
		21; 137:23-138:2; 138:4-6; 138:8-16; 138:18-		
		24; 139:1-4; 139:6; 139:8-12; 139:14-17;		
		139:19-22; 139:24-140:2; 140:4-9; 140:11-		
		13; 140:15; 140:17-20; 140:22-25; 141:2-6;		
		141:8-14; 141:16-18; 141:20; 141:22-142:1;		
		142:3-6; 142:8-13; 142:18-19; 142:21-23;		
		142:25; 143:3-5; 143:10-16; 143:18-20;		
		143:23-24; 144:1-5; 144:7-10; 144:12; 145:5-		
		9; 145:11-16; 145:18-23; 145:25-146:3;		
		146:5		

Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections
70:23-71:7		121:17-124:3; 124:6-7; 124:9-10; 124:12-15; 124:17-19; 124:21-23; 124:25-125:8; 125:10-12; 125:15-20; 125:22-126:2; 126:4-6; 126:8-9; 126:11-19; 126:21-127:3; 127:5-11; 127:13-20; ; 134:10-14; 134:16-20; 134:22-24; 135:1-3; 135:5; 135:11-18; 135:20-136:9; 136:11-17; 136:19-25; 137:2-5; 137:8-9; 137:11-13; 137:15-16; 137:18-21; 137:23-138:2; 138:4-6; 138:8-16; 138:18-24; 139:1-4; 139:6; 139:8-12; 139:14-17; 139:19-22; 139:24-140:2; 140:4-9; 140:11-13; 140:15; 140:17-20; 140:22-25; 141:2-6; 141:8-14; 141:16-18; 141:20; 141:22-142:1; 142:3-6; 142:8-13; 142:18-19; 142:21-23; 142:25; 143:3-5; 143:10-16; 143:18-20; 143:23-24; 144:1-5; 144:7-10; 144:12; 145:5-9; 145:11-16; 145:18-23; 145:25-146:3; 146:5	R, 403, BTS, BSD, PK, SPEC V, NARR, O, L

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW) Witness: Poplin, Ryan				
Date of Desposition: 2023-04-18 Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections	
71:14-72:25	NA, I	73:1-7; 124:6-7; 124:9-10; 124:12-15; 124:17-19; 124:21-23; 124:25-125:8; 125:10-12; 125:15-20; 125:22-126:2; 126:4-6; 126:8-9; 126:11-19; 126:21-127:3; 127:5-11; 127:13-20; 127:21-129:9; ; 134:10-14; 134:16-20; 134:22-24; 135:1-3; 135:5; 135:11-18; 135:20-136:9; 136:11-17; 136:19-25; 137:2-5; 137:8-9; 137:11-13; 137:15-16; 137:18-21; 137:23-138:2; 138:4-6; 138:8-16; 138:18-24; 139:1-4; 139:6; 139:8-12; 139:14-17; 139:19-22; 139:24-140:2; 140:4-9; 140:11-13; 140:15; 140:17-20; 140:22-25; 141:2-6; 141:8-14; 141:16-18; 141:20; 141:22-142:1; 142:3-6; 142:8-13; 142:18-19; 142:21-23; 142:25; 143:3-5; 143:10-16; 143:18-20; 143:23-24; 144:1-5; 144:7-10; 144:12; 145:5-9; 145:11-16; 145:18-23; 145:25-146:3; 146:5	R, 403, BTS, BSD, PK, SPEC V, NARR, O, L	

	of America Holdi	ng v. Natera, Inc. (Case No. 1:21-cv-00669-G	BW)	
Witness: Poplin, Ryan Date of Desposition: 2023-04-18				
Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections	
73:13-14	V, MIS	124:6-7; 124:9-10; 124:12-15; 124:17-19; 124:21-23; 124:25-125:8; 125:10-12; 125:15-20; 125:22-126:2; 126:4-6; 126:8-9; 126:11-19; 126:21-127:3; 127:5-11; 127:13-20; 127:21-129:9; ; 134:10-14; 134:16-20; 134:22-24; 135:1-3; 135:5; 135:11-18; 135:20-136:9; 136:11-17; 136:19-25; 137:2-5; 137:8-9; 137:11-13; 137:15-16; 137:18-21; 137:23-138:2; 138:4-6; 138:8-16; 138:18-24; 139:1-4; 139:6; 139:8-12; 139:14-17; 139:19-22; 139:24-140:2; 140:4-9; 140:11-13; 140:15; 140:17-20; 140:22-25; 141:2-6; 141:8-14; 141:16-18; 141:20; 141:22-142:1; 142:3-6; 142:8-13; 142:18-19; 142:21-23; 142:25; 143:3-5; 143:10-16; 143:18-20; 143:23-24; 144:1-5; 144:7-10; 144:12; 145:5-9; 145:11-16; 145:18-23; 145:25-146:3; 146:5	V, NARR, O, L	

Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections
73:16-74:10			R, 403, BTS,
		124:21-23; 124:25-125:8; 125:10-12; 125:15-	
			V, NARR, O, L
		19; 126:21-127:3; 127:5-11; 127:13-20;	
		127:21-129:9; ; 134:10-14; 134:16-20;	
		134:22-24; 135:1-3; 135:5; 135:11-18;	
		135:20-136:9; 136:11-17; 136:19-25; 137:2-	
		5; 137:8-9; 137:11-13; 137:15-16; 137:18-	
		21; 137:23-138:2; 138:4-6; 138:8-16; 138:18-	
		24; 139:1-4; 139:6; 139:8-12; 139:14-17;	
		139:19-22; 139:24-140:2; 140:4-9; 140:11-	
		13; 140:15; 140:17-20; 140:22-25; 141:2-6;	
		141:8-14; 141:16-18; 141:20; 141:22-142:1;	
		142:3-6; 142:8-13; 142:18-19; 142:21-23;	
		142:25; 143:3-5; 143:10-16; 143:18-20;	
		143:23-24; 144:1-5; 144:7-10; 144:12; 145:5-	
		9; 145:11-16; 145:18-23; 145:25-146:3;	
		146:5	

	Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Poplin, Ryan Date of Desposition: 2023-04-18					
Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections		
74:!6-75:10		124:6-7; 124:9-10; 124:12-15; 124:17-19; 124:21-23; 124:25-125:8; 125:10-12; 125:15-20; 125:22-126:2; 126:4-6; 126:8-9; 126:11-19; 126:21-127:3; 127:5-11; 127:13-20; 127:21-129:9; ; 134:10-14; 134:16-20; 134:22-24; 135:1-3; 135:5; 135:11-18; 135:20-136:9; 136:11-17; 136:19-25; 137:2-5; 137:8-9; 137:11-13; 137:15-16; 137:18-21; 137:23-138:2; 138:4-6; 138:8-16; 138:18-24; 139:1-4; 139:6; 139:8-12; 139:14-17; 139:19-22; 139:24-140:2; 140:4-9; 140:11-13; 140:15; 140:17-20; 140:22-25; 141:2-6; 141:8-14; 141:16-18; 141:20; 141:22-142:1; 142:3-6; 142:8-13; 142:18-19; 142:21-23; 142:25; 143:3-5; 143:10-16; 143:18-20; 143:23-24; 144:1-5; 144:7-10; 144:12; 145:5-9; 145:11-16; 145:18-23; 145:25-146:3; 146:5	R, 403, BTS, BSD, PK, SPEC, V, NARR, O, L		
75:14-76:18		76:19-21; 112:19-113:23; 113:25-116:6; 116:8-116:24; 117:2-4; 117:8-21; 117:23-25; 118:2-13; 118:17-119:17; 119:19-120:5; 120:7-17; 120:20-121:1; 121:3-16	R, 403, BTS, BSD, PK, SPEC		
74:4-79:10	MIS	112:19-113:23; 113:25-116:6; 116:8-116:24; 117:2-4; 117:8-21; 117:23-25; 118:2-13; 118:17-119:17; 119:19-120:5; 120:7-17; 120:20-121:1; 121:3-16; 124:6-7; 124:9-10; 124:12-15; 124:17-19; 124:21-23; 124:25-125:8; 125:10-12; 125:15-20; 125:22-126:2; 126:4-6; 126:8-9; 126:11-19; 126:21-127:3; 127:5-11; 127:13-20	R, 403, BTS, BSD, PK, SPEC		

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)			
Witness: Poplin, Ryan			
Date of Desposition: 2023-04-18 Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections
79:12-80:15	I	80:16-19; 80:21-23; 81:2-4; 81:6-9; 112:19- 113:23; 113:25-116:6; 116:8-116:24; 117:2- 4; 117:8-21; 117:23-25; 118:2-13; 118:17- 119:17; 119:19-120:5; 120:7-17; 120:20- 121:1; 121:3-16	R, 403, BTS, BSD, PK, SPEC
82:3-6	I	82:7-8; 82:10; 112:19-113:23; 113:25-116:6; 116:8-116:24; 117:2-4; 117:8-21; 117:23-25; 118:2-13; 118:17-119:17; 119:19-120:5; 120:7-17; 120:20-121:1; 121:3-16	
82:11-15	I, MIS	82:7-8; 82:10; 112:19-113:23; 113:25-116:6; 116:8-116:24; 117:2-4; 117:8-21; 117:23-25; 118:2-13; 118:17-119:17; 119:19-120:5; 120:7-17; 120:20-121:1; 121:3-16	
82:17-20	MIS	112:19-113:23; 113:25-116:6; 116:8-116:24; 117:2-4; 117:8-21; 117:23-25; 118:2-13; 118:17-119:17; 119:19-120:5; 120:7-17; 120:20-121:1; 121:3-16	R, 403, BTS, BSD, PK, SPEC
82:22	MIS	112:19-113:23; 113:25-116:6; 116:8-116:24; 117:2-4; 117:8-21; 117:23-25; 118:2-13; 118:17-119:17; 119:19-120:5; 120:7-17; 120:20-121:1; 121:3-16	R, 403, BTS, BSD, PK, SPEC

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Poplin, Ryan		7 (,	
Date of Desposition: 2023-04-18				
Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections	
82:25-83:19		83:20-84:1; 108:6-109:1; 134:10-14; 134:16-	R, 403, BTS,	
		20; 134:22-24; 135:1-3; 135:5; 135:11-18;	BSD, PK, SPEC,	
		135:20-136:9; 136:11-17; 136:19-25; 137:2-	V, NARR, O, L	
		5; 137:8-9; 137:11-13; 137:15-16; 137:18-		
		21; 137:23-138:2; 138:4-6; 138:8-16; 138:18-		
		24; 139:1-4; 139:6; 139:8-12; 139:14-17;		
		139:19-22; 139:24-140:2; 140:4-9; 140:11-		
		13; 140:15; 140:17-20; 140:22-25; 141:2-6;		
		141:8-14; 141:16-18; 141:20; 141:22-142:1;		
		142:3-6; 142:8-13; 142:18-19; 142:21-23;		
		142:25; 143:3-5; 143:10-16; 143:18-20;		
		143:23-24; 144:1-5; 144:7-10; 144:12; 145:5-		
		9; 145:11-16; 145:18-23; 145:25-146:3;		
		146:5-22; 146:24-147:3; 147:5-7; 147:9-10;		
		147:12-25; 148:2-7; 148:9-16; 148:9-16;		
		148:18-21; 148:23-149:23; 149:25-150:15;		
		150:17-151:4; 151:6-10; 151:12-21; 151:23-		
		152:1; 152:3; 152:12-153:8; 153:10-155:24;		
		156:1-2; 156:4-11; 156:13-17; 156:19-23;		
		156:25-157:2; 157:4; 157:8-15; 157:17-22;		
		157:24-158:3; 158:5-7; 158:9; 158:13-19;		
		158:21-159:8; 159:10-13; 159:15; 159:19-		
		160:1; 160:3-7; 160:9-23; 161:3-10; 161:12-		
		162:2; 162:13-16; 162:18; 162:20-24; 163:1-		
		4; 163:6		
84:2-5	V, MIS	85:4-9; 85:18-23; 152:12-153:8; 153:10-	R, 403, BTS,	
		155:24; 156:1-2; 156:4-11; 156:13-17;	BSD, PK, SPEC,	
		156:19-23; 156:25-157:2; 157:4; 157:8-15;	V, NARR, O, L	
		157:17-22; 157:24-158:3; 158:5-7; 158:9;		
		158:13-19; 158:21-159:8; 159:10-13;		
		159:15; 159:19-160:1; 160:3-7; 160:9-23;		
		161:3-10; 161:12-162:2; 162:13-16; 162:18;		
		162:20-24; 163:1-4; 163:6		

	Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Poplin, Ryan Date of Desposition: 2023-04-18					
Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections		
84:7		85:4-9; 85:18-23; 152:12-153:8; 153:10-155:24; 156:1-2; 156:4-11; 156:13-17; 156:19-23; 156:25-157:2; 157:4; 157:8-15; 157:17-22; 157:24-158:3; 158:5-7; 158:9; 158:13-19; 158:21-159:8; 159:10-13; 159:15; 159:19-160:1; 160:3-7; 160:9-23; 161:3-10; 161:12-162:2; 162:13-16; 162:18; 162:20-24; 163:1-4; 163:6	R, 403, BTS, BSD, PK, SPEC, V, NARR, O, L		
84:9-85:3		85:4-9; 85:18-23; 152:12-153:8; 153:10- 155:24; 156:1-2; 156:4-11; 156:13-17; 156:19-23; 156:25-157:2; 157:4; 157:8-15; 157:17-22; 157:24-158:3; 158:5-7; 158:9; 158:13-19; 158:21-159:8; 159:10-13; 159:15; 159:19-160:1; 160:3-7; 160:9-23; 161:3-10; 161:12-162:2; 162:13-16; 162:18; 162:20-24; 163:1-4; 163:6	R, 403, BTS, BSD, PK, SPEC, V, NARR, O, L		
85:24-86:3	MIS	152:12-153:8; 153:10-155:24; 156:1-2; 156:4-11; 156:13-17; 156:19-23; 156:25- 157:2; 157:4; 157:8-15; 157:17-22; 157:24- 158:3; 158:5-7; 158:9; 158:13-19; 158:21- 159:8; 159:10-13; 159:15; 159:19-160:1; 160:3-7; 160:9-23; 161:3-10; 161:12-162:2; 162:13-16; 162:18; 162:20-24; 163:1-4; 163:6	R, 403, BTS, BSD, PK, SPEC, V, NARR, O, L		
86:5-16	MIS	152:12-153:8; 153:10-155:24; 156:1-2; 156:4-11; 156:13-17; 156:19-23; 156:25- 157:2; 157:4; 157:8-15; 157:17-22; 157:24- 158:3; 158:5-7; 158:9; 158:13-19; 158:21- 159:8; 159:10-13; 159:15; 159:19-160:1; 160:3-7; 160:9-23; 161:3-10; 161:12-162:2; 162:13-16; 162:18; 162:20-24; 163:1-4; 163:6	R, 403, BTS, BSD, PK, SPEC, V, NARR, O, L		

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)					
Witness: Poplin, Ryan Date of Desposition: 2023-04-18	1 , 0				
Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections		
86:18-87:11	MIS	152:12-153:8; 153:10-155:24; 156:1-2; 156:4-11; 156:13-17; 156:19-23; 156:25-157:2; 157:4; 157:8-15; 157:17-22; 157:24-158:3; 158:5-7; 158:9; 158:13-19; 158:21-159:8; 159:10-13; 159:15; 159:19-160:1; 160:3-7; 160:9-23; 161:3-10; 161:12-162:2; 162:13-16; 162:18; 162:20-24; 163:1-4; 163:6	R, 403, BTS, BSD, PK, SPEC, V, NARR, O, L		
87:13-18	MIS	152:12-153:8; 153:10-155:24; 156:1-2; 156:4-11; 156:13-17; 156:19-23; 156:25-157:2; 157:4; 157:8-15; 157:17-22; 157:24-158:3; 158:5-7; 158:9; 158:13-19; 158:21-159:8; 159:10-13; 159:15; 159:19-160:1; 160:3-7; 160:9-23; 161:3-10; 161:12-162:2; 162:13-16; 162:18; 162:20-24; 163:1-4; 163:6	R, 403, BTS, BSD, PK, SPEC, V, NARR, O, L		
87:20-88:5	MIS	152:12-153:8; 153:10-155:24; 156:1-2; 156:4-11; 156:13-17; 156:19-23; 156:25-157:2; 157:4; 157:8-15; 157:17-22; 157:24-158:3; 158:5-7; 158:9; 158:13-19; 158:21-159:8; 159:10-13; 159:15; 159:19-160:1; 160:3-7; 160:9-23; 161:3-10; 161:12-162:2; 162:13-16; 162:18; 162:20-24; 163:1-4; 163:6	R, 403, BTS, BSD, PK, SPEC, V, NARR, O, L		
88:7-9	MIS	152:12-153:8; 153:10-155:24; 156:1-2; 156:4-11; 156:13-17; 156:19-23; 156:25-157:2; 157:4; 157:8-15; 157:17-22; 157:24-158:3; 158:5-7; 158:9; 158:13-19; 158:21-159:8; 159:10-13; 159:15; 159:19-160:1; 160:3-7; 160:9-23; 161:3-10; 161:12-162:2; 162:13-16; 162:18; 162:20-24; 163:1-4; 163:6	R, 403, BTS, BSD, PK, SPEC, V, NARR, O, L		

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)					
Witness: Poplin, Ryan Date of Desposition: 2023-04-18	1 , 0				
Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections		
89:14-90:1	MIS, V	152:12-153:8; 153:10-155:24; 156:1-2; 156:4-11; 156:13-17; 156:19-23; 156:25-157:2; 157:4; 157:8-15; 157:17-22; 157:24-158:3; 158:5-7; 158:9; 158:13-19; 158:21-159:8; 159:10-13; 159:15; 159:19-160:1; 160:3-7; 160:9-23; 161:3-10; 161:12-162:2; 162:13-16; 162:18; 162:20-24; 163:1-4; 163:6	R, 403, BTS, BSD, PK, SPEC, V, NARR, O, L		
90:3-7		152:12-153:8; 153:10-155:24; 156:1-2; 156:4-11; 156:13-17; 156:19-23; 156:25-157:2; 157:4; 157:8-15; 157:17-22; 157:24-158:3; 158:5-7; 158:9; 158:13-19; 158:21-159:8; 159:10-13; 159:15; 159:19-160:1; 160:3-7; 160:9-23; 161:3-10; 161:12-162:2; 162:13-16; 162:18; 162:20-24; 163:1-4; 163:6	R, 403, BTS, BSD, PK, SPEC, V, NARR, O, L		
100:3-15		100:16-23; 107:22-108:5; 110:7-111:1; 111:23-14; 129:12-130:6; 130:8-21; 130:23- 131:7; 131:9-132:1; 132:4-133:7; 133:9-18; 133:20-25; 134:2-8	R, 403, BTS, BSD, PK, SPEC		
101:3-102:9		102:10-13; 110:7-111:1; 111:23-14; 129:12-130:6; 130:8-21; 130:23-131:7; 131:9-132:1; 132:4-133:7; 133:9-18; 133:20-25; 134:2-8			
102:14-18	V, MIS	102:10-13; 110:7-111:1; 111:23-14; 129:12-130:6; 130:8-21; 130:23-131:7; 131:9-132:1; 132:4-133:7; 133:9-18; 133:20-25; 134:2-8			
102:20-103:13	V, MIS, C	110:7-111:1; 111:23-14; 129:12-130:6; 130:8-21; 130:23-131:7; 131:9-132:1; 132:4-133:7; 133:9-18; 133:20-25; 134:2-8	R, 403, BTS, BSD, PK, SPEC		

1 1	of America Holdi	ng v. Natera, Inc. (Case No. 1:21-cv-00669-G	BW)
Witness: Poplin, Ryan			
Date of Desposition: 2023-04-18 Labcorp's Opening Designations	Natera's Objections	Natera's Counter-Designations	Labcorp's Objections
103:14-18	V, MIS	110:7-111:1; 111:23-14; 129:12-130:6; 130:8-21; 130:23-131:7; 131:9-132:1; 132:4-133:7; 133:9-18; 133:20-25; 134:2-8	R, 403, BTS,
103:20-104:5		129:12-130:6; 130:8-21; 130:23-131:7; 131:9-132:1; 132:4-133:7; 133:9-18; 133:20-25; 134:2-8	R, 403, BTS, BSD, PK, SPEC
104:9-20		107:22-108:5; 111:2-20; 111:23-14; 129:12-130:6; 130:8-21; 130:23-131:7; 131:9-132:1; 132:4-133:7; 133:9-18; 133:20-25; 134:2-8	
105:9-106:11	MIS	111:2-20; 111:23-14; 129:12-130:6; 130:8- 21; 130:23-131:7; 131:9-132:1; 132:4-133:7; 133:9-18; 133:20-25; 134:2-8	R, 403, BTS, BSD, PK, SPEC
106:13-20		111:2-20; 111:23-14; 129:12-130:6; 130:8- 21; 130:23-131:7; 131:9-132:1; 132:4-133:7; 133:9-18; 133:20-25; 134:2-8	R, 403, BTS, BSD, PK, SPEC
107:3-21		129:12-130:6; 130:8-21; 130:23-131:7; 131:9-132:1; 132:4-133:7; 133:9-18; 133:20-25; 134:2-8	R, 403, BTS, BSD, PK, SPEC

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)					
Witness: Salari, Raheleh					
Date of Desposition: 2023-03-02	Date of Desposition: 2023-03-02				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
	Objections	Designations	Objections		
8:4-13		8:14-20			
10:4-6					
15:15-16		1612 21 17 22 10 14	D 402		
15:22-23		16:13-21; 17:22-18:14;	R, 403		
15.05.16.1		19:16-20:13	D 402		
15:25-16:1		16:13-21; 17:22-18:14;	R, 403		
20.0.15		19:16-20:13			
28:9-15					
34:7-22	Cmpd.	50.04.50.0.54.0.10.55.11	D 402 BY 0		
47:9-12		52:24-53:2; 54:3-13; 55:14-	R, 403, PK, O,		
47.16.17		20; 56:4-6	V, NARR		
47:16-17		52:24-53:2; 54:3-13; 55:14-	R, 403, PK, O,		
10.7.10		20; 56:4-6	V, NARR		
48:7-12		52:24-53:2; 54:3-13; 55:14-	R, 403, PK, O,		
10.10.40.4		20; 56:4-6	V, NARR		
48:19-49:4		52:24-53:2; 54:3-13; 55:14-	R, 403, PK, O,		
40.15.15	T	20; 56:4-6	V, NARR		
49:15-17	I	49:14; 49:18-21; 52:24-53:2;			
		54:3-13; 55:14-20; 56:4-6	OB, V, NARR		
49:22-50:17	I	50:18-22; 52:24-53:2; 54:3-	R, 403, PK, O,		
		13; 55:14-20; 56:4-6	OB, V, NARR		
50:25-51:19	Ι	50:18-22; 52:24-53:2; 54:3-	R, 403, PK, O,		
		13; 55:14-20; 56:4-6	OB, V, NARR		
51:21-52:13	Ι	50:18-22; 52:24-53:2; 54:3-	R, 403, PK, O,		
		13; 55:14-20; 56:4-6	OB, V, NARR		
56:13-15					
57:6-20					
58:6-8	V				
58:12-13					
58:17-22					
59:8-9					
60:8-62:3	V, 402, 403	63:5-21	R		
62:6-9	402, 403	63:5-21	R		
64:2-13					
65:2-24					
66:1-67:4		67:15-23; 54:3-13	R, 403, PK, V		
67:8-14		67:15-23; 54:3-13	R, 403, PK, V		
68:9-11	Cmpd., 701				
68:13-17					

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW) Witness: Salari, Raheleh Date of Desposition: 2023-03-02 Natera's Natera's Counter-Labcorp's **Labcorp's Opening Designations Objections Objections Designations** R, 403, PK, V 68:19-69:4 67:15-23; 54:3-13 69:23-70:14 70:23-24 71:5-12 71:22-72:5 72:6-15 R, NARR 75:6-7; 75:11-13; 75:15-24; 72:21-73:22 I, 402, 403 R, 403, NR, O 76:3-11; 76:14-15 74:1-2 I, 402, 403 75:6-7; 75:11-13; 75:15-24; R, 403, NR, O 76:3-11; 76:14-15 74:6-8 I, 402, 403 R, 403, NR, O 75:6-7; 75:11-13; 75:15-24; 76:3-11; 76:14-15 74:10-14 V, MIS, I, 402, 54:3-13; 75:6-7; 75:11-13; R, 403, PK, V, 403 75:15-24; 76:3-11; 76:14-15 NR, O 54:3-13; 75:6-7; 75:11-13; V, MIS, I, 402, R, 403, PK, V, 74:16-18 403 75:15-24; 76:3-11; 76:14-15 NR, O V, MIS, I, 402, 54:3-13; 75:6-7; 75:11-13; R, 403, PK, V, 74:23-25 403 75:15-24; 76:3-11; 76:14-15 NR, O 75:2-5 V, MIS, I 54:3-13; 75:6-7; 75:11-13; R, 403, PK, V, 75:15-24; 76:3-11; 76:14-15 NR, O 76:23-77:10 77:11-12; 77:14-17; 77:23-R, 403, O, H, 78:7; 78:14-22 NR, V, PK 83:18-19 83:23-84:2 84:14-25 87:1-6; 87:8-9; 87:11-15; R, 403 87:18-19; 87:21-23 85:2-86:2 R, 403 87:1-6; 87:8-9; 87:11-15; 87:18-19; 87:21-23 86:6 86:10-13 86:15-20 88:14-89:4 I, MIS, 402, 403 87:1-6; 87:8-9; 87:11-15; R, 403 87:18-19; 87:21-23 89:7-19 402, 403 87:1-6; 87:8-9; 87:11-15; R, 403 87:18-19; 87:21-23; 89:20-90:2 91:1-3 I, 402, 403 90:19-20; 90:22-25 R, 403

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Salari, Raheleh				
Date of Desposition: 2023-03-02	T		T	
Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections	
91:22-24				
92:2				
92:23-93:17				
93:19				
93:22				
93:24-94:2				
94:5				
94:9-95:14				
95:17-22				
95:25-96:5				
97:16-98:3				
98:6				
98:8-16				
99:20-22	MIS, V			
99:24	MIS, V			
100:2-101:9	402, 403	101:10-16; 101:19	R, 403, O	
101:24-102:1	Cmpd.	101:10-16; 101:19	R, 403, O	
102:4-16		101:10-16; 101:19	R, 403, O	
102:20-103:2		101:10-16; 101:19	R, 403, O	
103:4-9				
103:13				
103:16				
103:19-104:2	Ι	104:04		
104:7-12				
104:14-105:25	Cmpd.			
106:4-107:3	Cmpd.	130:11-132:2		
107:7-25	Cmpd.			
109:10-110:12	I, Cmpd.	101:10-16; 101:19; 108:22- 109:9; 111:9-11; 111:16- 112:8; 112:11; 112:20-113:8	R, 403, O, V, H	
113:13-19				
114:10-22		114:23-115:2; 115:5	R, 403, O, PK, H	
115:8-116:24	I, 602	114:23-115:2; 115:5; 11:1- 13; 11:18-21; 116:25-117:6; 117:10-11; 117:23-24	R, 403, O, PK, H, V	
118:20-23				
119:13-14				

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW) Witness: Salari, Raheleh			
Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections
120:2-5	·		
120:7-13			
122:10-14		122:15-20	
122:21-23		122:15-20	
123:4-5			
123:22	Ι	124:10-125:1; 125:2-14; 125:18-20; 127:3-5; 127:7- 12; 127:15-16	R, 403, O, PK, SPEC
123:25-124:4	I	124:10-125:1; 125:2-14; 125:18-20; 127:3-5; 127:7- 12; 127:15-16	R, 403, O, PK, SPEC
124:7-8	I	124:10-125:1; 125:2-14; 125:18-20; 127:3-5; 127:7- 12; 127:15-16	R, 403, O, PK, SPEC
128:5-6			
128:9-18			
129:3-16		130:11-132:2	R, 403, H, O, SPEC, PK, MIS
132:8-9			
132:13			

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)					
Witness: Wu, Hsin-Ta	*				
Date of Desposition: 2023-03-24	Date of Desposition: 2023-03-24				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
	Objections	Designations	Objections		
8:1-8		8:9-10	R, 403		
8:18-20					
12:14-14:3					
14:5-6					
17:11-14					
17:19-20					
17:22					
17:24-25		18:2-4; 18:7; 18:9	R, 403		
18:12-19					
19:6-10					
19:12-20					
20:3-5					
20:7-10					
20:23-22:16	V, Cmpd., 402,	20:17-22	R, 403		
	403				
23:9-16	S, 602				
23:21-25					
24:5-9	V, 402, 403				
27:5-7	V, 402, 403				
27:9-14	V, 402, 403	27:23-25			
27:16	V, 402, 403	27:23-25			
28:1-4	602	29:4-5; 29:7-10; 29:16-24;	R, 403, O, V, H		
		30:1-7			
28:7-13		29:4-5; 29:7-10; 29:16-24;	R, 403, O, V, H		
		30:1-7			
28:17-18	V, 701, S	29:4-5; 29:7-10; 29:16-24;	R, 403, O, V, H		
		30:1-7			
28:20-29:3	V, 701, S	29:4-5; 29:7-10; 29:16-24;	R, 403, O, V, H		
		30:1-7			
29:11-13	V, 701, S	29:4-5; 29:7-10; 29:16-24;	R, 403, O, V, H		
		30:1-7			
29:15	V, 701, S	29:4-5; 29:7-10; 29:16-24;	R, 403, O, V, H		
		30:1-7			
30:9-14	V	33:12-15; 33:20-24; 35:14-	R, 403, O, H		
		17; 35:19; 37:14-17			
30:18-23	V, MIS, 403	33:12-15; 33:20-24; 35:14-	R, 403, O, H		
		17; 35:19; 37:14-17			
30:25	V, MIS, 403	33:12-15; 33:20-24; 35:14-	R, 403, O, H		
		17; 35:19; 37:14-17			

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Wu, Hsin-Ta				
Date of Desposition: 2023-03-24				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
Labcorp's Opening Designations	Objections	Designations	Objections	
31:3-7	V	33:12-15; 33:20-24; 35:14-	R, 403, O, H	
		17; 35:19; 37:14-17		
31:9-18	V	33:12-15; 33:20-24; 35:14-	R, 403, O, H	
		17; 35:19; 37:14-17		
32:14-19	AF, 403			
32:22-33:4	402, 403, AF, 602			
33:6	402, 403, AF, 602			
34:13-17				
34:19-23				
34:25-35:10	V, MIS, 402, 403			
35:12-13		33:12-15; 33:20-24; 35:14- 17; 35:19; 37:14-17	R, 403, O, H	
35:20-22	Cmpd., V	35:25-36:5	R, 403	
35:24	Cmpd., V	35:25-36:5	R, 403	
36:8-10	V, HYP			
36:12-13	V, HYP			
36:16-18	V, HYP			
36:20-24	V, HYP			
37:18-25	V, 602			
38:2	V, 602			
38:16-23				
38:25-39:4				
39:6-8				
39:18-22	V			
39:24-40:10	Cmpd.			
40:12	Cmpd.			
42:6-11	V, MIS, I, AF	40:13-41:4; 41:6	R, 403, V, PK, H, NR	
42:13-15	I, AF	40:13-41:4; 41:6	R, 403, V, PK, H, NR	
43:22-44:1	NQP, I, AF	43:17-20; 44:2-3; 44:5-14	R, 403, V	
44:15-24	I, 602	45:1-3	R, 403	
45:4-8	I, 602	44:2-3; 44:5-14; 45:9-11	R, 403, V, NR	
45:18-20	602	,		
45:22	602			
46:15-47:3	403, 602, 701, MIS	46:9-11	R, 403	

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Wu, Hsin-Ta				
Date of Desposition: 2023-03-24				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
	Objections	Designations	Objections	
47:5-13	403, 602, 701,	46:9-11		
	MIS			
47:16-24	602, V	46:9-11		
48:1-8	403, 602, 701, V,	46:9-11		
	MIS			
48:10-15	403, 602, 701,	46:9-11		
	MIS			
48:17-24	403, 701, NBE,	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O	
	MIS	49:5-9; 49:11-15; 156:11-24;	V, H, BSD, PK	
		157:1; 157:2-17; 157:19-21;		
		157:23-159:6; 159:8-13;		
		159:15-24; 160:5-7; 160:9-		
		12; 160:14-17; 160:19-21;		
		160:23-25; 161:2-4; 161:6-8;		
		161:10		
49:16-18	403, 602, 701,	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O	
	MIS, NBE	49:5-9; 49:11-15; 157:2-17;	V, H, BSD, PK	
		157:19-21; 157:23-159:6;		
		159:8-13; 159:15-24; 160:5-		
		7; 160:9-12; 160:14-17;		
		160:19-21; 160:23-25; 161:2-		
		4; 161:6-8; 161:10		
49:20-24	403, 602, 701, I,	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O	
	Cmpd., MIS, NBE	49:5-9; 49:11-15; 157:2-17;	V, H, BSD, PK	
		157:19-21; 157:23-159:6;		
		159:8-13; 159:15-24; 160:5-		
		7; 160:9-12; 160:14-17;		
		160:19-21; 160:23-25; 161:2-		
		4; 161:6-8; 161:10		
50:1-51:5	403, 602, 701,	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O	
		49:5-9; 49:11-15; 157:2-17;	V, H, BSD, PK	
	1	157:19-21; 157:23-159:6;		
		159:8-13; 159:15-24; 160:5-		
		7; 160:9-12; 160:14-17;		
		160:19-21; 160:23-25; 161:2-		
		4; 161:6-8; 161:10		
		,		
	<u> </u>	<u> </u>	<u> </u>	

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)			
Witness: Wu, Hsin-Ta			
Date of Desposition: 2023-03-24 Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections
51:7-10	403, 602, 701, MIS, NBE	46:9-11; 48:25-49:1; 49:3; 49:5-9; 49:11-15; 157:2-17; 157:19-21; 157:23-159:6; 159:8-13; 159:15-24; 160:5- 7; 160:9-12; 160:14-17; 160:19-21; 160:23-25; 161:2- 4; 161:6-8; 161:10	R, 403, MIS, O V, H, BSD, PK
51:12-14	403, 602, 701, MIS, NBE	46:9-11; 48:25-49:1; 49:3; 49:5-9; 49:11-15; 157:2-17; 157:19-21; 157:23-159:6; 159:8-13; 159:15-24; 160:5- 7; 160:9-12; 160:14-17; 160:19-21; 160:23-25; 161:2- 4; 161:6-8; 161:10	R, 403, MIS, O V, H, BSD, PK
51:16-52:3	403, 602, 701, MIS, Cmpd., NBE	46:9-11; 48:25-49:1; 49:3; 49:5-9; 49:11-15; 157:2-17; 157:19-21; 157:23-159:6; 159:8-13; 159:15-24; 160:5- 7; 160:9-12; 160:14-17; 160:19-21; 160:23-25; 161:2- 4; 161:6-8; 161:10; 166:20- 25; 167:2-6	R, 403, MIS, O V, H, BSD, PK
52:5-9	403, 602, 701, MIS, Cmpd., NBE	46:9-11; 48:25-49:1; 49:3; 49:5-9; 49:11-15; 157:2-17; 157:19-21; 157:23-159:6; 159:8-13; 159:15-24; 160:5- 7; 160:9-12; 160:14-17; 160:19-21; 160:23-25; 161:2- 4; 161:6-8; 161:10; 166:20- 25; 167:2-6	R, 403, MIS, O V, H, BSD, PK

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Wu, Hsin-Ta				
Date of Desposition: 2023-03-24				
Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections	
52:11-15	403, 602, 701, MIS	46:9-11; 48:25-49:1; 49:3; 49:5-9; 49:11-15; 157:2-17; 157:19-21; 157:23-159:6; 159:8-13; 159:15-24; 160:5- 7; 160:9-12; 160:14-17; 160:19-21; 160:23-25; 161:2- 4; 161:6-8; 161:10	R, 403, MIS, O V, H, BSD, PK	
53:16-54:13	403, 602, 701, MIS			
54:15-18	403, 602, 701, MIS			
54:20-55:2				
55:4-6				
55:8-14	NA, I	55:15		
55:16-56:10	V			
56:12-16	V			
56:22-57:2	V, MIS			
57:4-7	402, 403, V, MIS			
57:9	402, 403, V, MIS			
57:22-24	402, 403, V, MIS			
58:1-3	402, 403, V, MIS			
58:5-12	Cmpd., V			
58:14-20		63:2-4; 63:6-10; 63:12-17	R, 403, O, H, NR	
59:7-15				
59:19-24	602			
60:10-24	602, MIS			
61:7-13	602, S			
63:18-64:8	V, MIS, AF, 602	63:2-4; 63:6-10; 63:12-17	R, 403, O, H, NR	
64:10-14	V, MIS, AF, 602	63:2-4; 63:6-10; 63:12-17	R, 403, O, H, NR	
64:16-21	V, MIS, AF, 602, 701			

Labcorp Corporation of Ame	rica Holding v. Na	tera, Inc. (Case No. 1:21-cv-0	0669-GBW)
Witness: Wu, Hsin-Ta			
Date of Desposition: 2023-03-24			
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's
Labeor p's Opening Designations	Objections	Designations	Objections
64:23-65:14	V, MIS, AF, 602,		
	701		
65:16			
66:1-5	V, MIS, 602, 701		
66:7-8	V, MIS, 602, 701		
66:10-22	V, MIS, 602, 701		
67:19-68:6			
68:8-18	Cmpd.		
68:20-69:1	403, 602, 802	69:2; 69:4; 69:15-17	R, 403, MIS
69:5-10	403, 602, 802	69:2; 69:4; 69:15-17	R, 403, MIS
69:18-20	403, 602, 802, HYP	69:2; 69:4; 69:15-17	R, 403, MIS
69:22	403, 602, 802	69:2; 69:4; 69:15-17	R, 403, MIS
70:7-8	403, 602, 802	69:2; 69:4; 69:15-17; 73:11-	R, 403, O, MIS,
		13; 73:15-17	Н
70:10-12	403, 602, 802	69:2; 69:4; 69:15-17; 73:11-	R, 403, O, MIS,
		13; 73:15-17	Н
70:22-71:3	403, 602, 802, V	69:2; 69:4; 69:15-17; 73:11-	R, 403, O, MIS,
		13; 73:15-17	Н
71:6-20	403, 602, 802, V,	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O
	MIS	49:5-9; 49:11-15; 69:2; 69:4;	V, H, BSD, PK
		69:15-17; 73:11-13; 73:15-	
		17; 156:11-24; 157:1; 157:2-	
		17; 157:19-21; 157:23-	
		159:6; 159:8-13; 159:15-24;	
		160:5-7; 160:9-12; 160:14-	
		17; 160:19-21; 160:23-25;	
		161:2-4; 161:6-8; 161:10	

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Wu, Hsin-Ta				
Date of Desposition: 2023-03-24				
I shows to On wise Design of the second	Natera's	Natera's Counter-	Labcorp's	
Labcorp's Opening Designations	Objections	Designations	Objections	
71:22-72:9	403, 602, 701,	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O	
	802, V, MIS, NBE	49:5-9; 49:11-15; 69:2; 69:4;	V, H, BSD, PK	
		69:15-17; 73:11-13; 73:15-		
		17; 156:11-24; 157:1; 157:2-		
		17; 157:19-21; 157:23-		
		159:6; 159:8-13; 159:15-24;		
		160:5-7; 160:9-12; 160:14-		
		17; 160:19-21; 160:23-25;		
		161:2-4; 161:6-8; 161:10		
72:11-73:3	403, 602, 701,	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O	
		49:5-9; 49:11-15; 73:11-13;	V, H, BSD, PK	
		73:15-17; 156:11-24; 157:1;	, , ,	
		157:2-17; 157:19-21; 157:23-		
		159:6; 159:8-13; 159:15-24;		
		160:5-7; 160:9-12; 160:14-		
		17; 160:19-21; 160:23-25;		
		161:2-4; 161:6-8; 161:10		
		,		
73:5-8	403, 602, 701,	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O	
		49:5-9; 49:11-15; 73:11-13;	V, H, BSD, PK	
		73:15-17; 156:11-24; 157:1;	, , ,	
		157:2-17; 157:19-21; 157:23-		
		159:6; 159:8-13; 159:15-24;		
		160:5-7; 160:9-12; 160:14-		
		17; 160:19-21; 160:23-25;		
		161:2-4; 161:6-8; 161:10		
		- ,		
73:10	403, 602, 701,	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O	
		49:5-9; 49:11-15; 73:11-13;	V, H, BSD, PK	
	002, 1,11112,1122	73:15-17; 156:11-24; 157:1;	, , 11, 222, 111	
		157:2-17; 157:19-21; 157:23-		
		159:6; 159:8-13; 159:15-24;		
		160:5-7; 160:9-12; 160:14-		
		17; 160:19-21; 160:23-25;		
		161:2-4; 161:6-8; 161:10		
		., 101.0 0, 101.10		

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Wu, Hsin-Ta				
Date of Desposition: 2023-03-24				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
	Objections	Designations	Objections	
73:18-74:7		46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O	
	MIS, NBE	49:5-9; 49:11-15; 156:11-24;	V, H, BSD, PK	
		157:1; 157:2-17; 157:19-21;		
		157:23-159:6; 159:8-13;		
		159:15-24; 160:5-7; 160:9-		
		12; 160:14-17; 160:19-21;		
		160:23-25; 161:2-4; 161:6-8;		
		161:10; 166:20-25; 167:2-6		
74:9-11	403, 602, 701, V,	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O	
	MIS, NBE	49:5-9; 49:11-15; 156:11-24;	V, H, BSD, PK	
		157:1; 157:2-17; 157:19-21;		
		157:23-159:6; 159:8-13;		
		159:15-24; 160:5-7; 160:9-		
		12; 160:14-17; 160:19-21;		
		160:23-25; 161:2-4; 161:6-8;		
		161:10; 166:20-25; 167:2-6		
74:13-15	403, 602, 701, V,	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O	
	MIS	49:5-9; 49:11-15; 156:11-24;		
		157:1; 157:2-17; 157:19-21;		
		157:23-159:6; 159:8-13;		
		159:15-24; 160:5-7; 160:9-		
		12; 160:14-17; 160:19-21;		
		160:23-25; 161:2-4; 161:6-8;		
		161:10; 166:20-25; 167:2-6		
74:17	403, 602, 701, V,	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O	
1,	MIS	49:5-9; 49:11-15; 156:11-24;		
		157:1; 157:2-17; 157:19-21;	, , ,	
		157:23-159:6; 159:8-13;		
		159:15-24; 160:5-7; 160:9-		
		12; 160:14-17; 160:19-21;		
		160:23-25; 161:2-4; 161:6-8;		
		161:10; 166:20-25; 167:2-6		
74:24-75:1	403, 701, V, MIS	75:21; 75:23-25; 76:5-9;	R, 403, O	
	, , , , , , , , , , , , , , , , , ,	76:16-18; 76:20	12.,,	
75:3-7	403, 701, V, MIS	75:21; 75:23-25; 76:5-9;	R, 403, O	
		76:16-18; 76:20		

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW) Witness: Wu, Hsin-Ta					
					Date of Desposition: 2023-03-24
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
Labcorp's Opening Designations	Objections	Designations	Objections		
75:9	403, 701, V, MIS	75:21; 75:23-25; 76:5-9;	R, 403, O		
		76:16-18; 76:20			
75:15-18	403, V, MIS	75:21; 75:23-25; 76:5-9;	R, 403, O		
		76:16-18; 76:20			
75:20		75:21; 75:23-25; 76:5-9;	R, 403, O		
		76:16-18; 76:20			
76:23-77:5					
77:11-13					
77:15-22					
77:24-78:2	403, V, MIS	78:5-8; 78:15-17; 78:19	R, 403, O, NR		
78:4	403, V, MIS	78:5-8; 78:15-17; 78:19	R, 403, O, NR		
78:9-11	403, V, MIS	78:5-8; 78:15-17; 78:19	R, 403, O, NR		
78:13-14	403, V, MIS	78:5-8; 78:15-17; 78:19	R, 403, O, NR		
80:14-20	403, 602, 802	69:2; 69:4; 69:15-17	R, 403, MIS		
81:1-3	403, 602, 802, V,	69:2; 69:4; 69:15-17	R, 403, MIS		
	MIS, I				
81:5-15	403, 602, 802, V,	69:2; 69:4; 69:15-17	R, 403, MIS		
	MIS				
81:17	403, 602, 802, V,	69:2; 69:4; 69:15-17	R, 403, MIS		
	MIS				
82:1-8	403, 602, 802, V,	69:2; 69:4; 69:15-17	R, 403, MIS		
	MIS				
82:10-16	403, 602, 802, V,	82:19-20	R		
	MIS, I				
82:23-83:5	AF				
83:7-84:4	602, 701, V, MIS,				
	AF				
84:6-9	602, 701, V, MIS				
84:11-19	602, 701, V, MIS				
84:21-85:9	402, 403, 602,				
	MIS				
85:11-14	402, 403, 602,				
	MIS				
85:16-19	402, 403, 602,				
	MIS, HYP, NBE,				
	S				
85:21-86:1	402, 403, MIS				
86:3-4	403, MIS				

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)					
Witness: Wu, Hsin-Ta					
Date of Desposition: 2023-03-24					
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
1 1 0 0	Objections	Designations	Objections		
86:6-10	403, MIS, HYP, S,				
	NBE				
86:12-15	403, MIS				
86:17-19	403, MIS				
86:21-25	403, MIS				
87:2-4	403, MIS				
87:6-7	403, MIS, S, HYP,				
	602				
87:9-19	403, V, MIS, S				
	HYP, 602				
87:21-88:15	403, V, MIS				
88:17-22					
89:1-3	V				
89:5-8	I	89:9-10; 89:12-16; 89:18-	R, 403, H, O		
		90:6; 90:12; 90:16-17; 90:19-			
		20; 90:23-24; 91:1-5; 91:7-			
		10; 91:12			
89:11	I	89:9-10; 89:12-16; 89:18-	R, 403, H, O		
		90:6; 90:12; 90:16-17; 90:19-			
		20; 90:23-24; 91:1-5; 91:7-			
		10; 91:12			
92:1-4	Cmpd.	92:14-17	Н		
92:6-13		92:14-17	Н		
92:18-23					
92:25-93:6	MIS				
93:8-11	AF				
93:13-14					
94:6-10	Cmpd.				
94:12-15	Cmpd., I, NA	94:17-22; 94:24-95:5; 95:7-9	R, 403, O, SPEC		
95:10-11	V				
95:13-14	V				
95:21-23					
95:25-96:14	MIS	97:1-9	R, NR		
96:16-25	MIS, AF				
97:12-14					
97:16-25					
98:2-4					
98:6-24					
99:1-19	V, MIS				

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)					
Witness: Wu, Hsin-Ta					
Date of Desposition: 2023-03-24					
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
	Objections	Designations	Objections		
99:21-24	403, 701, V, MIS	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O		
		49:5-9; 49:11-15; 156:11-24;	V, H, BSD, PK		
		157:1; 157:2-17; 157:19-21;			
		157:23-159:6; 159:8-13;			
		159:15-24; 160:5-7; 160:9-			
		12; 160:14-17; 160:19-21;			
		160:23-25; 161:2-4; 161:6-8;			
		161:10			
100:1-5	403, 701, V, MIS	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O		
		49:5-9; 49:11-15; 156:11-24;	V, H, BSD, PK		
		157:1; 157:2-17; 157:19-21;			
		157:23-159:6; 159:8-13;			
		159:15-24; 160:5-7; 160:9-			
		12; 160:14-17; 160:19-21;			
		160:23-25; 161:2-4; 161:6-8;			
		161:10			
100:7	403, 701, V, MIS		R, 403, MIS, O		
	103, 701, 7,17113	49:5-9; 49:11-15; 156:11-24;			
		157:1; 157:2-17; 157:19-21;	V, 11, D5D, 1 K		
		157:23-159:6; 159:8-13;			
		159:15-24; 160:5-7; 160:9-			
		12; 160:14-17; 160:19-21;			
		160:23-25; 161:2-4; 161:6-8;			
		161:10			
100:12-13	403, 701, V, MIS	101.10			
100.12-13	1403, 701, V, WIIS				
100:15-17	403, 701, V, MIS				
100.13 17	103, 701, 1, 11115				
100:19-20	403, 701, V, MIS				
100.19 20	103, 701, 1, 11113				
100:22	403, 701, V, MIS				
100.22	1403, 701, v , WIIS				
100:24-25	403, 701, V, MIS				
	, , , , , , , , , , , , , , , , , ,				
101:2-5	403, 701, V, MIS				
	,,.,.,.,.,.,.,.,.,.,.,.,.,.,.,.,.,.,				
101:7-9	403, 701, V, MIS				
	.55, 751, 7, 17115				
101:11-15	403, 701, V, MIS				
	, , , , , , , , , , , , , , , , , ,				
<u></u>	1	<u> </u>			

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
	Witness: Wu, Hsin-Ta			
Date of Desposition: 2023-03-24 Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections	
101:17-22	403, 701, V, MIS	9	3	
101:24-102:8	403, 602, 701, V, MIS	103:2-5; 103:7-8; 103:10-19	R, 403, O, H	
102:10-24	602	103:2-5; 103:7-8; 103:10-19	R, 403, O, H	
103:1	602	103:2-5; 103:7-8; 103:10-19	R, 403, O, H	
103:20-104:1	Cmpd.			
104:3	Cmpd.			
104:5-7	Ι	104:9-10	R, 403	
104:12-17	I, MIS	10:9-10	R, 403	
104:19-24	MIS		,	
105:1-11	602	105:20-22	R, 403	
105:14-17	602	105:20-22	R, 403	
105:19	602	105:20-22	R, 403	
105:23	602, S	105:20-22	R, 403	
105:25-106:2	602, S	105:20-22; 105:3-4; 105:6	R, 403	
106:25	403, 602, S	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O	
100.23	103, 002, 5	49:5-9; 49:11-15; 105:20-22;		
		105:3-4; 105:6; 157:2-17;		
		157:19-21; 157:23-159:6;		
		159:8-13; 159:15-24; 160:5-		
		7; 160:9-12; 160:14-17;		
		160:19-21; 160:23-25; 161:2-		
		4; 161:6-8; 161:10		
107:2	403, 602, S	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O	
		49:5-9; 49:11-15; 105:20-22;	V, H, BSD, PK	
		105:3-4; 105:6; 157:2-17;		
		157:19-21; 157:23-159:6;		
		159:8-13; 159:15-24; 160:5-		
		7; 160:9-12; 160:14-17;		
		160:19-21; 160:23-25; 161:2-		
		4; 161:6-8; 161:10		

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)					
Witness: Wu, Hsin-Ta					
Date of Desposition: 2023-03-24	Date of Desposition: 2023-03-24				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's		
Labeot p's Opening Designations	Objections	Designations	Objections		
107:4-13	403, 602, S	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O		
		49:5-9; 49:11-15; 105:20-22;	V, H, BSD, PK		
		105:3-4; 105:6; 157:2-17;			
		157:19-21; 157:23-159:6;			
		159:8-13; 159:15-24; 160:5-			
		7; 160:9-12; 160:14-17;			
		160:19-21; 160:23-25; 161:2-			
		4; 161:6-8; 161:10			
107:15-17	403, 602, S	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O		
		49:5-9; 49:11-15; 105:20-22;	V, H, BSD, PK		
		105:3-4; 105:6; 157:2-17;			
		157:19-21; 157:23-159:6;			
		159:8-13; 159:15-24; 160:5-			
		7; 160:9-12; 160:14-17;			
		160:19-21; 160:23-25; 161:2-			
		4; 161:6-8; 161:10			
107:19-22	403, 602, S	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O		
		49:5-9; 49:11-15; 105:20-22;	V, H, BSD, PK		
		105:3-4; 105:6; 157:2-17;			
		157:19-21; 157:23-159:6;			
		159:8-13; 159:15-24; 160:5-			
		7; 160:9-12; 160:14-17;			
		160:19-21; 160:23-25; 161:2-			
		4; 161:6-8; 161:10			
107:24-108:4	403, 602, S		R, 403, MIS, O		
		49:5-9; 49:11-15; 105:20-22;	V, H, BSD, PK		
		105:3-4; 105:6; 157:2-17;			
		157:19-21; 157:23-159:6;			
		159:8-13; 159:15-24; 160:5-			
		7; 160:9-12; 160:14-17;			
		160:19-21; 160:23-25; 161:2-			
		4; 161:6-8; 161:10			

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)			
Witness: Wu, Hsin-Ta			
Date of Desposition: 2023-03-24	1		
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's
	Objections	Designations	Objections
108:6-13	403, 602, S,	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O
	Cmpd.	49:5-9; 49:11-15; 105:20-22;	V, H, BSD, PK
		105:3-4; 105:6; 157:2-17;	
		157:19-21; 157:23-159:6;	
		159:8-13; 159:15-24; 160:5-	
		7; 160:9-12; 160:14-17;	
		160:19-21; 160:23-25; 161:2-	
		4; 161:6-8; 161:10	
108:15-19	403, 602, S, I, NA	108:21-22	R, 403
109:3-4	403, 602, S, I	108:21-24; 109:1-2	R, 403
109:6-14	403, 602, S, I	108:21-24; 109:1-2	R, 403
109:16-18	403, 602, S, I		
109:20-24	403, 602, 701,		
	MIS		
110:1-4	403, 602, 701,		
	MIS		
111:7-112:15	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS	106:3-4; 106:6; 161:11-19;	V, H, BSD, PK
		161:21-162:17; 162:19-	
		163:1	
112:17-22	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS	106:3-4; 106:6; 161:11-19;	V, H, BSD, PK
		161:21-162:17; 162:19-	
		163:1	
112:24-113:2	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS	106:3-4; 106:6; 161:11-19;	V, H, BSD, PK
		161:21-162:17; 162:19-	
		163:1	
113:4-8	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS	106:3-4; 106:6; 161:11-19;	V, H, BSD, PK
		161:21-162:17; 162:19-	
		163:1	
113:22-25	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS	106:3-4; 106:6; 161:11-19;	V, H, BSD, PK
		161:21-162:17; 162:19-	
		163:1	

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Wu, Hsin-Ta				
Date of Desposition: 2023-03-24	T		T	
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
	Objections	Designations	Objections	
114:2-7	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 161:11-19;	V, H, BSD, PK	
		161:21-162:17; 162:19-		
		163:1		
114:9-12	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 161:11-19;	V, H, BSD, PK	
		161:21-162:17; 162:19-		
		163:1		
114:14-19	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 161:11-19;	V, H, BSD, PK	
		161:21-162:17; 162:19-		
		163:1		
114:21	403, 602, 701,			
	MIS			
114:25-115:2				
115:4-9	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 115:15-16;	V, H, BSD, PK	
		115:18; 161:11-19; 161:21-		
		162:17; 162:19-163:1		
115:11-14	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 115:15-16;	V, H, BSD, PK	
		115:18; 161:11-19; 161:21-		
		162:17; 162:19-163:1		
115:21-116:10	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 115:15-16;	V, H, BSD, PK	
		115:18; 161:11-19; 161:21-		
		162:17; 162:19-163:1		
116:12-17	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 115:15-16;	V, H, BSD, PK	
		115:18; 161:11-19; 161:21-		
		162:17; 162:19-163:1		
116:19-24	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 115:15-16;	V, H, BSD, PK	
		115:18; 161:11-19; 161:21-		
		162:17; 162:19-163:1		
117:1-3	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 115:15-16;	V, H, BSD, PK	
		115:18; 161:11-19; 161:21-		
		162:17; 162:19-163:1		

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)			
Witness: Wu, Hsin-Ta			
Date of Desposition: 2023-03-24			
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's
Labeor p's Opening Designations	Objections	Designations	Objections
117:5-9	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS	106:3-4; 106:6; 115:15-16;	V, H, BSD, PK
		115:18; 161:11-19; 161:21-	
		162:17; 162:19-163:1	
117:11-24	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS	106:3-4; 106:6; 161:11-19;	V, H, BSD, PK
		161:21-162:17; 162:19-	
		163:1	
118:1-7		36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
		106:3-4; 106:6; 161:11-19;	V, H, BSD, PK
		161:21-162:17; 162:19-	
		163:1	
118:12-15			
118:18-20			
118:24-119:2			
119:6-7			
119:9-19	403, 602, 701,		
	MIS		
120:2-3	403, 602, 701,		
	MIS		
120:5-8	403, 602, 701,		
	MIS		
120:13-20	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS	106:3-4; 106:6; 120:21-23;	V, H, BSD, PK
		161:11-19; 161:21-162:17;	
		162:19-163:1	
120:24-121:1	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS	106:3-4; 106:6; 120:21-23;	V, H, BSD, PK
		161:11-19; 161:21-162:17;	
		162:19-163:1	
121:3-6	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS	106:3-4; 106:6; 120:21-23;	V, H, BSD, PK
		161:11-19; 161:21-162:17;	
		162:19-163:1	
121:8-10	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS	106:3-4; 106:6; 120:21-23;	V, H, BSD, PK
		122:14-15; 122:17-18;	
		161:11-19; 161:21-162:17;	
		162:19-163:1	

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)			
Witness: Wu, Hsin-Ta			
Date of Desposition: 2023-03-24	NT 4	N. () C	T 1 .
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's
121:12-14	Objections	Designations	Objections D. 402 MIS O
121:12-14	403, 602, 701, MIS	36:3-5; 40:13-41:4; 41:6; 106:3-4; 106:6; 120:21-23;	R, 403, MIS, O V, H, BSD, PK
	MIS	122:14-15; 122:17-18;	V, 11, DSD, FK
		161:11-19; 161:21-162:17;	
		162:19-163:1	
121:16-19	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS	106:3-4; 106:6; 120:21-23;	V, H, BSD, PK
		122:14-15; 122:17-18;	
		161:11-19; 161:21-162:17;	
		162:19-163:1	
121:21-23	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS	106:3-4; 106:6; 120:21-23;	V, H, BSD, PK
		122:14-15; 122:17-18;	
		161:11-19; 161:21-162:17;	
		162:19-163:1	
121:25-122:1	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS	106:3-4; 106:6; 120:21-23;	V, H, BSD, PK
		122:14-15; 122:17-18;	
		161:11-19; 161:21-162:17;	
122:4-13	403, 602, 701,	162:19-163:1 36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
122.4-13	MIS	106:3-4; 106:6; 120:21-23;	V, H, BSD, PK
	WIIS	122:14-15; 122:17-18;	V, 11, D3D, 1 K
		161:11-19; 161:21-162:17;	
		162:19-163:1	
122:19-20	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS	106:3-4; 106:6; 120:21-23;	V, H, BSD, PK
		122:14-15; 122:17-18;	
		161:11-19; 161:21-162:17;	
		162:19-163:1	
122:22-123:1	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS, I	106:3-4; 106:6; 120:21-23;	V, H, BSD, PK
		122:14-15; 122:17-18; 123:4-	
		5; 123:7; 161:11-19; 161:21-	
		162:17; 162:19-163:1	

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)			
Witness: Wu, Hsin-Ta			
Date of Desposition: 2023-03-24	1		
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's
	Objections	Designations	Objections
123:9-16	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS, I	106:3-4; 106:6; 120:21-23;	V, H, BSD, PK
		122:14-15; 122:17-18; 123:4-	
		5; 123:7; 161:11-19; 161:21-	
		162:17; 162:19-163:1	
123:18-19	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS	106:3-4; 106:6; 120:21-23;	V, H, BSD, PK
		122:14-15; 122:17-18; 123:4-	· · · · · · · · · · · · · · · · · · ·
		5; 123:7; 161:11-19; 161:21-	
		162:17; 162:19-163:1	
123:21-124:5	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS, I	106:3-4; 106:6; 120:21-23;	V, H, BSD, PK
		122:14-15; 122:17-18; 123:4-	
		5; 123:7; 124:6-7; 124:9-11;	
		161:11-19; 161:21-162:17;	
		162:19-163:1	
124:12-14	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS, I	106:3-4; 106:6; 123:4-5;	V, H, BSD, PK
		123:7; 124:6-7; 124:9-11;	
		161:11-19; 161:21-162:17;	
		162:19-163:1	
124:16-125:8	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS, I	106:3-4; 106:6; 123:4-5;	V, H, BSD, PK
		123:7; 124:6-7; 124:9-11;	
		161:11-19; 161:21-162:17;	
125.10	402 (02 701	162:19-163:1	D 402 MIC O
125:10	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS, I	106:3-4; 106:6; 123:4-5; 123:7; 124:6-7; 124:9-11;	V, H, BSD, PK
		161:11-19; 161:21-162:17;	
		162:19-163:1	
125:17-20	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS, I	106:3-4; 106:6; 123:4-5;	V, H, BSD, PK
	ĺ	123:7; 124:6-7; 124:9-11;	,
		161:11-19; 161:21-162:17;	
		162:19-163:1	

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)			0669-GBW)
Witness: Wu, Hsin-Ta			
Date of Desposition: 2023-03-24			
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's
Labcorp's Opening Designations	Objections	Designations	Objections
125:22-25	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS, I	106:3-4; 106:6; 123:4-5;	V, H, BSD, PK
		123:7; 124:6-7; 124:9-11;	
		161:11-19; 161:21-162:17;	
		162:19-163:1	
126:2-7	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS, I	106:3-4; 106:6; 123:4-5;	V, H, BSD, PK
		123:7; 124:6-7; 124:9-11;	
		161:11-19; 161:21-162:17;	
		162:19-163:1	
126:9-14	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS, I, NBE	106:3-4; 106:6; 123:4-5;	V, H, BSD, PK
		123:7; 124:6-7; 124:9-11;	
		161:11-19; 161:21-162:17;	
		162:19-163:1	
126:16-20	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O
	MIS, NBE, Cmpd.	49:11-15; 46:9-11; 48:25-	V, H, BSD, PK
		49:1; 49:3; 49:5-9; 106:3-4;	
		106:6; 123:4-5; 123:7; 124:6-	
		7; 124:9-11; 156:11-24;	
		157:1; 157:2-17; 157:19-21;	
		157:23-159:6; 159:8-13;	
		159:15-24; 160:5-7; 160:9-	
		12; 160:14-17; 160:19-21;	
		160:23-25; 161:2-4; 161:6-8;	
		161:10-19; 161:21-162:17;	
		162:19-163:1; 166:20-25;	
		167:2-6	

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Wu, Hsin-Ta				
Date of Desposition: 2023-03-24				
	Natera's	Natera's Counter-	Labcorp's	
Labcorp's Opening Designations	Objections	Designations	Objections	
126:22-24	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS, NBE, Cmpd.	49:11-15; 46:9-11; 48:25-	V, H, BSD, PK	
		49:1; 49:3; 49:5-9; 106:3-4;		
		106:6; 123:4-5; 123:7; 124:6-		
		7; 124:9-11; 128:12-15;		
		128:17-18; 128:21-22;		
		156:11-24; 157:1; 157:2-17;		
		157:19-21; 157:23-159:6;		
		159:8-13; 159:15-24; 160:5-		
		7; 160:9-12; 160:14-17;		
		160:19-21; 160:23-25; 161:2-		
		4; 161:6-8; 161:10-19;		
		161:21-162:17; 162:19-		
		163:1; 166:20-25; 167:2-6		
127:1-128:3	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 128:12-15;	V, H, BSD, PK	
		128:17-18; 128:21-22;		
		161:11-19; 161:21-162:17;		
		162:19-163:1		
128:5-8	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 128:12-15;	V, H, BSD, PK	
		128:17-18; 128:21-22;		
		161:11-19; 161:21-162:17;		
		162:19-163:1		
128:10-11	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 128:12-15;	V, H, BSD, PK	
		128:17-18; 128:21-22;		
		161:11-19; 161:21-162:17;		
120 22 120 2	100 600 501	162:19-163:1	D 400 1470 0	
128:23-129:2	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 128:12-15;	V, H, BSD, PK	
		128:17-18; 128:21-22; 129:9-		
		10; 129:12; 161:11-19;		
		161:21-162:17; 162:19-		
		163:1		

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Wu, Hsin-Ta				
Date of Desposition: 2023-03-24				
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
	Objections	Designations	Objections	
129:4-6	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 128:12-15;	V, H, BSD, PK	
		128:17-18; 128:21-22; 129:9-		
		10; 129:12; 161:11-19;		
		161:21-162:17; 162:19-		
		163:1		
129:8	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 128:12-15;	V, H, BSD, PK	
		128:17-18; 128:21-22; 129:9-		
		10; 129:12; 161:11-19;		
		161:21-162:17; 162:19-		
120.10.20	100 600 501	163:1	D 400 1470 0	
129:18-20	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 129:9-10;	V, H, BSD, PK	
		129:12; 161:11-19; 161:21-		
120 22 120 1	102 (02 501	162:17; 162:19-163:1	D 402 NGG 0	
129:22-130:1	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 129:9-10;	V, H, BSD, PK	
		129:12; 161:11-19; 161:21-		
120.2.5	402 (02 701	162:17; 162:19-163:1	D 402 MIC O	
130:3-5	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 128:12-15;	V, H, BSD, PK	
		128:17-18; 128:21-22; 129:9-		
		10; 129:12; 161:11-19; 161:21-162:17; 162:19-		
		163:1		
130:7-9		36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
130.7-9		106:3-4; 106:6; 128:12-15;	V, H, BSD, PK	
		128:17-18; 128:21-22; 129:9-	· · · · · · · · · · · · · · · · · · ·	
		10; 129:12; 161:11-19;		
		161:21-162:17; 162:19-		
		163:1		
130:11-131:3	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 128:12-15;	V, H, BSD, PK	
		128:17-18; 128:21-22; 129:9-		
		10; 129:12; 161:11-19;		
		161:21-162:17; 162:19-		
		163:1		
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Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)				
Witness: Wu, Hsin-Ta				
Date of Desposition: 2023-03-24	Date of Desposition: 2023-03-24			
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's	
Labcorp's Opening Designations	Objections	Designations	Objections	
131:5-11	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 128:12-15;	V, H, BSD, PK	
		128:17-18; 128:21-22; 129:9-		
		10; 129:12; 161:11-19;		
		161:21-162:17; 162:19-		
		163:1		
131:13-18	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 128:12-15;	V, H, BSD, PK	
		128:17-18; 128:21-22; 129:9-		
		10; 129:12; 161:11-19;		
		161:21-162:17; 162:19-		
		163:1		
131:20-132:9	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 128:12-15;	V, H, BSD, PK	
		128:17-18; 128:21-22; 129:9-		
		10; 129:12; 161:11-19;		
		161:21-162:17; 162:19-		
		163:1		
132:15	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 132:16-17;	V, H, BSD, PK	
		132:19-20; 161:11-19;		
		161:21-162:17; 162:19-		
		163:1		
132:21-133:1	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 132:16-17;	V, H, BSD, PK	
		132:19-20; 161:11-19;		
		161:21-162:17; 162:19-		
		163:1		
133:3	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 132:16-17;	V, H, BSD, PK	
		132:19-20; 161:11-19;		
		161:21-162:17; 162:19-		
		163:1		
133:8-10	403, 602, 701,	36:3-5; 40:13-41:4; 41:6;	R, 403, MIS, O	
	MIS	106:3-4; 106:6; 132:16-17;	V, H, BSD, PK	
		132:19-20; 161:11-19;		
		161:21-162:17; 162:19-		
		163:1		

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)			
Witness: Wu, Hsin-Ta			
Date of Desposition: 2023-03-24			
Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections
133:12-15	403, 602, 701, MIS	36:3-5; 40:13-41:4; 41:6; 106:3-4; 106:6; 132:16-17; 132:19-20; 161:11-19; 161:21-162:17; 162:19- 163:1	R, 403, MIS, O V, H, BSD, PK
133:17-22	403, 602, 701, MIS	36:3-5; 40:13-41:4; 41:6; 106:3-4; 106:6; 132:16-17; 132:19-20; 161:11-19; 161:21-162:17; 162:19- 163:1	R, 403, MIS, O V, H, BSD, PK
133:24-134:4	403, 602, 701, MIS	36:3-5; 40:13-41:4; 41:6; 106:3-4; 106:6; 132:16-17; 132:19-20; 161:11-19; 161:21-162:17; 162:19- 163:1	R, 403, MIS, O V, H, BSD, PK
134:6-8	403, 602, 701, MIS	36:3-5; 40:13-41:4; 41:6; 106:3-4; 106:6; 132:16-17; 132:19-20; 161:11-19; 161:21-162:17; 162:19- 163:1	R, 403, MIS, O V, H, BSD, PK
134:10-14	403, 602, 701, MIS	36:3-5; 40:13-41:4; 41:6; 106:3-4; 106:6; 132:16-17; 132:19-20; 161:11-19; 161:21-162:17; 162:19- 163:1	R, 403, MIS, O V, H, BSD, PK
134:16-22	802	36:3-5; 40:13-41:4; 41:6; 106:3-4; 106:6; 161:11-19; 161:21-162:17; 162:19- 163:1	R, 403, MIS, O V, H, BSD, PK
134:24	802	36:3-5; 40:13-41:4; 41:6; 106:3-4; 106:6; 161:11-19; 161:21-162:17; 162:19- 163:1	R, 403, MIS, O V, H, BSD, PK
135:2-8	403, 602, 701, MIS		
135:10-20	403, 602, 701, I, MIS	135:22-24	R, 403
136:7-8	403, 602, 701, I, MIS	135:22-24	R, 403

Labcorp Corporation of Ame	rica Holding v. Na	atera, Inc. (Case No. 1:21-cv-0	00669-GBW)
Witness: Wu, Hsin-Ta			
Date of Desposition: 2023-03-24			
Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections
137:4-7	403, 602, 701,	136:9-12; 136:14-16	R, 403
	MIS, V		
137:9-11	403, 602, 701,	136:9-12; 136:14-16	R, 403
	MIS, V		
137:13-16	403, 602, 701,	136:9-12; 136:14-16	R, 403
	MIS, V, Cmpd.		
137:18	403, 602, 701,	136:9-12; 136:14-16	R, 403
	MIS, V, Cmpd.		
137:20-23	_	136:9-12; 136:14-16	R, 403
137:25-138:3	802	136:9-12; 136:14-16	R, 403
138:5-7	802	136:9-12; 136:14-16	R, 403
142:22-143:4		144:8-9; 144:11-14; 144:16-	R, 403
		17	
143:7-11		144:8-9; 144:11-14; 144:16- 17	R, 403
143:13-25		144:8-9; 144:11-14; 144:16- 17	R, 403
144:5-7		144:8-9; 144:11-14; 144:16- 17	R, 403
145:4-6	Cmpd.		
145:8-10	emp u .		
145:12-15			
145:17-18			
145:20-24			
146:1-3			
146:6-7			
154:23-25			
155:2-7			
163:8-23		105:3-4; 105:6; 164:14;	R, 403, MIS, O
		164:16-19; 164:21; 164:23- 25	V, H, BSD, PK
164:9-13		105:3-4; 105:6; 164:14;	R, 403, MIS, O
		164:16-19; 164:21; 164:23-	V, H, BSD, PK
		25	

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)			
Witness: Wu, Hsin-Ta			
Date of Desposition: 2023-03-24			
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's
1 1 0 0	Objections	Designations	Objections
165:15-18	403, 602, 701,	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O
	MIS, V	49:5-9; 49:11-15; 156:11-24;	V, H, BSD, PK
		157:1; 157:2-17; 157:19-21;	
		157:23-159:6; 159:8-13;	
		159:15-24; 160:5-7; 160:9-	
		12; 160:14-17; 160:19-21;	
		160:23-25; 161:2-4; 161:6-8;	
		161:10; 166:20-25; 167:2-6	
165:20-25			R, 403, MIS, O
		49:5-9; 49:11-15; 156:11-24;	V, H, BSD, PK
		157:1; 157:2-17; 157:19-21;	
		157:23-159:6; 159:8-13;	
		159:15-24; 160:5-7; 160:9-	
		12; 160:14-17; 160:19-21;	
		160:23-25; 161:2-4; 161:6-8;	
		161:10; 166:20-25; 167:2-6	
167:20-25	403, 602, 701,	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O
107.20 23	MIS, V, I, NBE	49:5-9; 49:11-15; 156:11-24;	
	, , , , , , , , , , , , , , ,	157:1; 157:2-17; 157:19-21;	, , 11, 222, 111
		157:23-159:6; 159:8-13;	
		159:15-24; 160:5-7; 160:9-	
		12; 160:14-17; 160:19-21;	
		160:23-25; 161:2-4; 161:6-8;	
		161:10; 166:20-25; 167:2-6;	
		168:1-2; 168:4	
168:5-11		46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O
		49:5-9; 49:11-15; 156:11-24;	V, H, BSD, PK
		157:1; 157:2-17; 157:19-21;	
		157:23-159:6; 159:8-13;	
		159:15-24; 160:5-7; 160:9-	
		12; 160:14-17; 160:19-21;	
		160:23-25; 161:2-4; 161:6-8;	
		161:10; 166:20-25; 167:2-6;	
		168:1-2; 168:4; 168:12-13;	
		168:15	

Labcorp Corporation of America Holding v. Natera, Inc. (Case No. 1:21-cv-00669-GBW)			
Witness: Wu, Hsin-Ta			
Date of Desposition: 2023-03-24			
Labcorp's Opening Designations	Natera's	Natera's Counter-	Labcorp's
Labcorp's Opening Designations	Objections	Designations	Objections
168:16-24	403, 602, 701,	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O
	MIS, V, I	49:5-9; 49:11-15; 156:11-24;	V, H, BSD, PK
		157:1; 157:2-17; 157:19-21;	
		157:23-159:6; 159:8-13;	
		159:15-24; 160:5-7; 160:9-	
		12; 160:14-17; 160:19-21;	
		160:23-25; 161:2-4; 161:6-8;	
		161:10; 166:20-25; 167:2-6;	
		168:1-2; 168:4; 168:12-13;	
		168:15; 169:6-8	
169:1-3	403, 602, 701,		R, 403, MIS, O
	MIS, V, I	49:5-9; 49:11-15; 156:11-24;	V, H, BSD, PK
		157:1; 157:2-17; 157:19-21;	
		157:23-159:6; 159:8-13;	
		159:15-24; 160:5-7; 160:9-	
		12; 160:14-17; 160:19-21;	
		160:23-25; 161:2-4; 161:6-8;	
		161:10; 166:20-25; 167:2-6;	
		168:1-2; 168:4; 168:12-13;	
		168:15; 169:6-8	
169:5	403, 602, 701,	46:9-11; 48:25-49:1; 49:3;	R, 403, MIS, O
109.3	MIS, V, I	49:5-9; 49:11-15; 156:11-24;	
	WII5, v, I	157:1; 157:2-17; 157:19-21;	V, 11, DSD, 1 K
		157:23-159:6; 159:8-13;	
		159:15-24; 160:5-7; 160:9-	
		12; 160:14-17; 160:19-21;	
		160:23-25; 161:2-4; 161:6-8;	
		161:10; 166:20-25; 167:2-6;	
		168:1-2; 168:4; 168:12-13;	
		168:15; 169:6-8	
		100.13, 107.0-0	
169:22-170:3	403, 602, 701,		
	MIS, V, I		
170:5-8	403, 602, 701,		
	MIS, V, I, S,		
	Cmpd.		

Labcorp Corporation of Ame	rica Holding v. Nate	ra, Inc. (Case No. 1:21-cv-	00669-GBW)
Witness: Wu, Hsin-Ta	g		,
Date of Desposition: 2023-03-24			
Labcorp's Opening Designations	Natera's Objections	Natera's Counter- Designations	Labcorp's Objections
170:10-14	403, 602, 701, MIS, V, I, S,	<u> </u>	
170:16-23	Cmpd. 403, 602, 701, MIS, V, I, S		
170:25-171:7	403, 602, 701, MIS, V, I, S		
171:19	403, 602, 701, MIS, V, I, S		
171:21	403, 602, 701, MIS, V, I, S		
171:23	403, 602, 701, MIS, V, I, S		

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 227 of 739 PageID

EXHIBIT 9

AA	Asked and answered; Fed. R. Evid. 611(a).
ARG	Argumentative, or attorney argument; Fed. R. Evid. 611(a).
BTS	Beyond the scope of examination or of 30(b)(6) topic; Fed R. Evid. 611, Fed. R. Civ. P. 30(b)(6).
BSD	Counter-Designation Beyond the Scope of the Designation(s).
СР	Compound question.
F	No foundation or assumes facts not in evidence; Fed. R. Evid. 602, 703, 901.
FOW	An objection to form is waived if it was not timely made during the deposition, Fed. R. Civ. P. 32(d)(3)(B).
Н	Hearsay if offered for the truth of the matter asserted; Fed. R. Evid. 801, 803, 805.
I	Incomplete designation; Fed. R. Evid. 106, 403.
IH	Incomplete Hypothetical.
L	Leading; Fed. R. Evid. 611(c).
LC	Calls for Legal Conclusion; Fed. R. Evid. 701.
LW	Witness will be testifying live at trial.
MIL	Subjec to motion in limine
MIS	Mischaracterization of testimony or evidence.
NARR	Narrative.
NR	Not responsive; Fed. R. Evid. 611(a).
0	Unqualified Opinion; Calls for improper expert opinion from lay witness; Fed. R. Evid. 701, 702.
ОВ	Attorney Objection improperly designated/Improper designation.
Р	Privileged; Fed. R. Evid. 501, Fed. R. Civ. P. 26(b)(3),(4).
PK	Lack of personal knowledge; Fed. R. Evid. 602.
R	Not relevant; Fed. R. Evid. 401, 402.
SPEC	Calls for Speculation; Fed. R. Evid. 602, 701, 702.
403	Unfairly prejudicial; cumulative, waste of time, Fed. R. Evid. 403.
V	Vague or ambiguous; Fed. R. Evid. 611(a).

AA	Asked and answered; Fed. R. Evid. 611(a).
ARG	Argumentative, or attorney argument; Fed. R. Evid. 611(a).
BTS	Beyond the scope of examination or of 30(b)(6) topic; Fed R. Evid. 611, Fed. R. Civ. P. 30(b)(6).
BSD	Counter-Designation Beyond the Scope of the Designation(s).
СР	Compound question.
F	No foundation or assumes facts not in evidence; Fed. R. Evid. 602, 703, 901.
FOW	An objection to form is waived if it was not timely made during the deposition, Fed. R. Civ. P. 32(d)(3)(B).
Н	Hearsay if offered for the truth of the matter asserted; Fed. R. Evid. 801, 803, 805.
I	Incomplete designation; Fed. R. Evid. 106, 403.
IH	Incomplete Hypothetical.
L	Leading; Fed. R. Evid. 611(c).
LC	Calls for Legal Conclusion; Fed. R. Evid. 701.
LW	Witness will be testifying live at trial.
MIL	Subject to motion in limine.
MIS	Mischaracterization of testimony or evidence.
NARR	Narrative.
NR	Not responsive; Fed. R. Evid. 611(a).
0	Unqualified Opinion; Calls for improper expert opinion from lay witness; Fed. R. Evid. 701, 702.
ОВ	Attorney Objection improperly designated/Improper designation.
Р	Privileged; Fed. R. Evid. 501, Fed. R. Civ. P. 26(b)(3),(4).
PK	Lack of personal knowledge; Fed. R. Evid. 602.
R	Not relevant; Fed. R. Evid. 401, 402.
SPEC	Calls for Speculation; Fed. R. Evid. 602, 701, 702.
403	Unfairly prejudicial; cumulative, waste of time, Fed. R. Evid. 403.
V	Vague or ambiguous; Fed. R. Evid. 611(a).

Witness	Natera	Labcorp Objections	Labcorp Counter-Designations	Natera
	Designations	,		Objections
Freivogel, Mary		R, 403		
Freivogel, Mary	007:05-007:14	· ·		
Freivogel, Mary		R, 403, SPEC, PK, O, F		
Freivogel, Mary		R, 403, SPEC, PK, O, F		
Freivogel, Mary		R, 403, SPEC, PK, O, CP, V, F		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary	_	R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary	+	R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V, MIS		
<u> </u>				
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, O, F, V		
Freivogel, Mary		R, 403, SPEC, PK, F, V		
Freivogel, Mary		R, 403, SPEC, PK, F, V		
Freivogel, Mary		R, 403, SPEC, PK, F, V		
Freivogel, Mary	+	R, 403, SPEC, PK, F, V		
Freivogel, Mary		R, 403, SPEC, PK, F, V		
Freivogel, Mary		R, 403, SPEC, PK, F, V		
Freivogel, Mary		R, 403, SPEC, PK, F, V		
Freivogel, Mary		R, 403, SPEC, PK, F, V		
Freivogel, Mary		R, 403, SPEC, PK, V		
Freivogel, Mary		R, 403, SPEC, V, PK		
Freivogel, Mary	044:14-045:18	R, 403, SPEC, V, PK	46:23-47:14	Н
Freivogel, Mary		R, 403, SPEC, V, PK	46:23-47:14	Н
Freivogel, Mary		R, 403, SPEC, V, PK, F	46:23-47:14	Н
Freivogel, Mary		R, 403, SPEC, V, PK, F	46:23-47:14; 51:15-17; 51:25-52:07; 52:09-20	BSD, H
Freivogel, Mary		R, 403, SPEC, V, PK, F, CP	46:23-47:14; 51:15-17; 51:25-52:07; 52:09-20	BSD, H
Freivogel, Mary	050:08-050:14	R, 403, SPEC, V, PK, F, CP	46:23-47:14; 51:15-17; 51:25-52:07; 52:09-20	BSD, H
Freivogel, Mary	050:16-050:23	R, 403, SPEC, V, PK, F, CP	46:23-47:14; 51:15-17; 51:25-52:07; 52:09-20	BSD, H
Freivogel, Mary	053:03-053:05	R, 403, SPEC, V, PK, F	53:24-54:1; 54:03-06; 54:10-12; 54:14-18	BSD, H
Freivogel, Mary	053:08-053:23	R, 403, SPEC, V, PK, F	53:24-54:1; 54:03-06; 54:10-12; 54:14-18	BSD, H
Freivogel, Mary	054:19-055:14	R, 403, SPEC, V, PK, F	53:24-54:1; 54:03-06; 54:10-12; 54:14-18	BSD, H
Freivogel, Mary		R, 403, V, SPEC, PK, F		
Freivogel, Mary	056:11-056:15	R, 403, V, SPEC, PK, F		
Freivogel, Mary	056:17-057:12	R, 403, SPEC, PK, F, V		
Freivogel, Mary	057:14-057:25	R, 403, SPEC, PK, F, V, I		

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 231 of 739 PageID Fig. vg 2009 Fig. vg 2019 Filed 08/27/25 Page 231 of 739 PageID Fig. vg 2019 Filed 08/27/25 Page 231 of 739 PageID Filed 08/27/25 Page 231 of 739 PageID Fig. vg 2019 Filed 08/27/25 Page 231 of 739 PageID Filed 08/27/25 PageID Filed 08/27/2

Witness	Natera	Labcorp Objections	Labcorp Counter-Designations	Natera
	Designations			Objections
Freivogel, Mary	058:02-058:03	R, 403, SPEC, PK, F, V, I		
Freivogel, Mary	058:05-058:10	R, 403, SPEC, PK, F, V		
Freivogel, Mary	058:12-059:20	R, 403, SPEC, PK, F, V		
Freivogel, Mary	059:22-059:22	R, 403, SPEC, PK, F, V		
Freivogel, Mary	059:24-059:25	R, 403, SPEC, PK, F, V, I		
Freivogel, Mary	060:02-060:04	R, 403, SPEC, PK, F, V, I		
Freivogel, Mary	060:10-061:04	R, 403, SPEC, PK, F, V		
Freivogel, Marv	061:06-062:09	R. 403. SPEC. PK. F. V		

Witness	Natera	Labcorp Objections	Labcorp Counter-Designations	Natera Objections
L. d. Bishand	Designations			
Lusk, Richard Lusk, Richard	008:07-009:19 011:10-011:13			
Lusk, Richard	011:10-011:13			
Lusk, Richard	012:20-013:24	CP. 403		
Lusk, Richard	014:02-014:05			
Lusk, Richard	015:24-017:06			
Lusk, Richard	018:07-018:11			
Lusk, Richard	019:05-019:09			
Lusk, Richard	020:05-021:15		19:19-22	H, I, MIS, R, 403
Lusk, Richard	023:10-025:24		19:19-22; 127:23-128:16 19:19-22; 127:23-128:16	BSD, H, I, MIS, R, L, 403
Lusk, Richard Lusk, Richard	026:05-026:18 026:20-027:09	NARR, CP	19:19-22; 127:23-128:16	BSD, H, I, MIS, R, L, 403 BSD, H, I, MIS, R, L, 403
Lusk, Richard	030:17-032:16		19.19-22, 127.23-128.10	B3D, 11, 1, 19113, 11, 1, 403
Lusk, Richard	033:07-034:09	CP,V, R, 403		
Lusk, Richard	034:12-036:24			
Lusk, Richard	037:02-037:17	SPEC, PK V, R, 403		
Lusk, Richard	037:19-038:15	CP, I, MIS, NARR, PK, SPEC, PK V, R, 403		
Lusk, Richard		CP, I, MIS, NARR, PK, SPEC, PK V, R, 403		
Lusk, Richard		Withdrawn, BTS, CP, MIS, NARR, PK, SPEC, PK V, R, 403		
Lusk, Richard		BTS, MIS, NARR, R, 403, V		
Lusk, Richard Lusk, Richard		BTS, MIS, NARR, R, 403, V F, MIS, NARR, SPEC, PK V, R, 403	+	
Lusk, Richard		MIS, NARR, SPEC, PK V, R, 403	<u> </u>	
Lusk, Richard		MIS, NARR, V, R, 403	127:23-128:16	BSD, H, L
Lusk, Richard		MIS, NARR, SPEC, PK PK, V, R, 403	50:9-10; 127:23-128:16	BSD, H, L, I, V
Lusk, Richard	049:14-050:08	MIS, NARR, SPEC, PK PK, V, R, 403	50:9-10	
Lusk, Richard	050:11-050:14			
Lusk, Richard	051:14-054:23			
Lusk, Richard		MIS, NARR, SPEC, PK PK, V, R, 403	126:18-127:22	BSD, H, L
Lusk, Richard		MIS, NARR, SPEC, PK PK, V, R, 403	126:18-127:22	BSD, H, L
Lusk, Richard Lusk, Richard		MIS, NARR, SPEC, PK PK V, R, 403 MIS, NARR, SPEC, PK PK, V, R, 403	126:18-127:22 126:18-127:22	BSD, H, L BSD, H, L
Lusk, Richard		MIS, NARR, SPEC, PK PK, V, R, 403	120.10-127.22	D3D, 11, L
Lusk, Richard		MIS, NARR, SPEC, PK PK, V, R, 403		
Lusk, Richard		MIS, NARR, SPEC, PK PK, V, R, 403		
Lusk, Richard	065:22-066:02	MIS, NARR, SPEC, PK PK, V, R, 403		
Lusk, Richard	066:11-068:05	V		
Lusk, Richard	068:08-068:13			
Lusk, Richard		MIS, NARR, OB, SPEC, PK PK, V, R, 403	71:11-13	
Lusk, Richard Lusk, Richard	071:14-071:18	SPEC, PK PK, V, R, 403	71:11-13	
Lusk, Richard	074:24-075:12	1		
Lusk, Richard		SPEC, PK PK V, R, 403		
Lusk, Richard		SPEC, PK PK V, R, 403		
Lusk, Richard		SPEC, PK PK V, R, 403		
Lusk, Richard		SPEC, PK V, R, 403		
Lusk, Richard		OB, SPEC, PK V, R, 403		
Lusk, Richard		SPEC, PK V, R, 403		
Lusk, Richard Lusk, Richard	082:20-084:09 084:24-086:15	SPEC, PK V, R, 403		
Lusk, Richard		SPEC, PK V, R, 403	86:16-21	BSD, H
Lusk, Richard		SPEC, PK V, R, 403	86:16-21	BSD, H
Lusk, Richard		SPEC, PK V, R, 403	86:16-21	BSD, H
Lusk, Richard		SPEC, PK V, R, 403	86:16-21	BSD, H
Lusk, Richard		SPEC, PK V, R, 403		
Lusk, Richard		SPEC, PK V, R, 403		
Lusk, Richard		BTS, F, SPEC, PK V, R, 403	400 47 00 400 00 00 00	
Lusk, Richard		BTS, MIS, NARR, OB, R, 403, SPEC, PK V	106:17-20; 106:22-23; 106:25-107:7	BSD, H
Lusk, Richard Lusk, Richard		MIS, NARR, OB, R, 403, SPEC, PK V MIS, NARR, R, 403, SPEC, PK V	106:17-20; 106:22-23; 106:25-107:7 106:17-20; 106:22-23; 106:25-107:7	BSD, H BSD, H
Lusk, Richard	106:05-106:06		106:17-20; 106:22-23; 106:25-107:7	BSD, H
Lusk, Richard	107:08-107:11	, -, -, -, -	106:17-20; 106:22-23; 106:25-107:7	BSD, H
Lusk, Richard	108:17-108:21		.,	,
Lusk, Richard		SPEC, PK V, R, 403		
Lusk, Richard		AA, SPEC, PK V, R, 403		
Lusk, Richard		AA, SPEC, PK V, R, 403		
Lusk, Richard		SPEC, PK V, R, 403, MIL		
Lusk, Richard		SPEC, PK V, R, 403, MIL		
Lusk, Richard		SPEC, PK V, R, 403, MIL		
Lusk, Richard		SPEC, PK V, R, 403, MIL		
Lusk, Richard	121:23-122:05	SPEC, PK V, R, 403, MIL		1

Witness	Natera	Labcorp Objections	Labcorp Counter-Designations	Natera Objections
	Designations			
Lusk, Richard	122:16-123:03	SPEC, PK, V, R, 403, MIL		
Lusk, Richard	123:05-124:03	BTS, SPEC, PK V, R, 403, MIL		
Lusk, Richard	124:06-124:13	BTS, SPEC, PK V, R, 403, MIL		
Lusk, Richard	124:15-124:19	BTS, SPEC, PK V, R, 403, MIL		
Lusk Richard	124:21-124:21	BTS SPEC PK V. R. 403 MII		

Witness	Natera	Labcorp Objections	Labcorp Counter-Designations	Natera Objections
	Designations			
Malani, Nirav	006:12-008:02			
Malani, Nirav	010:07-013:15	R, 403		
Malani, Nirav	024:12-024:22			
Malani, Nirav	026:20-027:02			
Malani, Nirav	027:16-027:19			
Malani, Nirav	027:21-028:12	AA, V, R, 403		
Malani, Nirav	028:19-029:06 029:20-030:23			
Malani, Nirav Malani, Nirav	034:06-034:08	V R 403		
Malani, Nirav	034:12-036:05			
Malani, Nirav		MIS, NARR, V, R, 403		
Malani, Nirav	037:16-037:19	, ., ., .,		
Malani, Nirav	038:14-038:19			
Malani, Nirav	044:14-044:15	F, V, R, 403		
Malani, Nirav	044:17-045:18	F, MIS, V, R, 403		
Malani, Nirav	045:20-046:06	F, V, R, 403		
Malani, Nirav	046:09-046:20			
Malani, Nirav	054:18-055:16	,		
Malani, Nirav	058:18-059:11	, ,	64:21-67:21	BSD, H, 403
Malani, Nirav		O, PK, SPEC, V, R, 403 O, PK, SPEC, V, R, 403	64:21-67:21 64:21-67:21	BSD, H, 403
Malani, Nirav Malani, Nirav		- 	64:21-67:21	BSD, H, 403
Malani, Nirav		MIS, SPEC, V, R, 403 MIS, SPEC, V, R, 403	64:21-67:21	BSD, H, 403 BSD, H, 403
Malani, Nirav	063:14-063:19		64:21-67:21	BSD, H, 403
Malani, Nirav	063:21-064:12		64:21-67:21	BSD, H, 403
Malani, Nirav		CP, MIS, SPEC, V, R, 403		
Malani, Nirav		CP, MIS, SPEC, V, R, 403		
Malani, Nirav	070:14-070:18	CP, MIS, NARR, V, R, PK, 403		
Malani, Nirav	070:20-070:25	CP, MIS, NARR, V, R, PK, SPEC, 403		
Malani, Nirav	071:24-072:05	OB, CP, MIS, NARR, V, PK, R, 403		
Malani, Nirav		CP, MIS, NARR, R, 403, SPEC, V		
Malani, Nirav		O, CP, MIS, NARR, R, 403, SPEC, V		
Malani, Nirav		O, MIS, NARR, R, 403, SPEC, V		
Malani, Nirav		O, MIS, NARR, R, 403, SPEC, V		
Malani, Nirav	083:05-088:21	R, 403, V		
Malani, Nirav Malani, Nirav	088:23-089:11 090:25-092:08		92:9-93:15	Н
Malani, Nirav	090:23-092:08	R 403 V PK	92:9-93:15	
Malani, Nirav	098:13-098:17		92:9-93:15	BSD, H
Malani, Nirav	099:08-099:13		92:9-93:15	BSD, H
Malani, Nirav	099:16-102:16		92:9-93:15	BSD, H
Malani, Nirav	105:03-108:18	R, 403, V, PK	92:9-93:15	BSD, H
Malani, Nirav	109:07-109:18	R, 403, V, PK, CP		
Malani, Nirav	112:08-112:15	R, 403, V, PK	109:25-111:10	BSD, H
Malani, Nirav	113:23-115:04			
Malani, Nirav	126:03-126:14	R, 403, V, PK	121:3-5; 121:7-122:14; 124:10-128:2.	BSD, H, 403
Malani, Nirav	127:22-127:25			
Malani, Nirav	128:19-129:23			
Malani, Nirav	133:24-134:23 134:25-136:13			
Malani, Nirav Malani, Nirav		R, 403, V, PK, SPEC		
Malani, Nirav		MIS, NARR, SPEC, V, R, 403		
Malani, Nirav		MIS, NARR, SPEC, V, R, 403	 	
Malani, Nirav	144:25-145:11			
Malani, Nirav	148:02-148:08			
Malani, Nirav		MIS, NARR, SPEC, V, R, 403		
Malani, Nirav	159:13-161:07	MIS, NARR, SPEC, V, R, 403		_
Malani, Nirav	162:17-162:18	F, MIS, SPEC, V, R, 403	161:8-23; 161:25-162:16; 183:22-25; 184:3-6	BSD, H, 403
Malani, Nirav		F, MIS, SPEC, V, R, 403	161:8-23; 161:25-162:16; 183:22-25; 184:3-6	BSD, H, 403
Malani, Nirav		F, MIS, SPEC, V, R, 403	161:8-23; 161:25-162:16; 183:22-25; 184:3-6	BSD, H, 403
Malani, Nirav		MIS, NARR, SPEC, V, R, 403, LC, O		
Malani, Nirav	_	MIS, NARR, SPEC, V, R, 403, LC, O		
Malani, Nirav		MIS, NARR, SPEC, V. R. 403, LC, O		
Malani, Nirav Malani, Nirav		MIS, NARR, SPEC, V, R, 403, LC, O MIS, NARR, SPEC, V, R, 403, LC, O		
iviaiaiii, iVII dV	107.10-107.11	IVII.3, IVANN, 3FLC, V, N, 4U3, LC, U		

Witness	Natera	Labcorp Objections	Labcorp Counter-Designations	Natera Objections
	Designations			•
Malani, Nirav	170:15-170:17			
Malani, Nirav	170:24-172:08			
Malani, Nirav	175:08-175:12			
Malani, Nirav	175:15-175:17			
Malani, Nirav	175:19-175:23			
Malani, Nirav		BTS, SPEC, PK, V, R, 403		
Malani, Nirav	_	BTS, SPEC, PK, V, R, 403		
Malani, Nirav	+	BTS, SPEC, PK, V, R, 403		
Malani, Nirav		BTS, SPEC, PK, V, R, 403		
Malani, Nirav		BTS, SPEC, PK, LC, O, V, R, 403		
Malani, Nirav		SPEC, V, R, 403, LC, O		
, ,				
Malani, Nirav		SPEC, V, R, 403		
Malani, Nirav	+	O, SPEC, V, R, 403		
Malani, Nirav	+	O, SPEC, V, R, 403		
Malani, Nirav		O, SPEC, V, R, 403		
Malani, Nirav		O, SPEC, V, R, 403		
Malani, Nirav	207:04-207:07			
Malani, Nirav	207:14-207:16			
Malani, Nirav		NARR, PK, R, 403		
Malani, Nirav		NARR, PK, R, 403		
Malani, Nirav	212:10-212:20			
Malani, Nirav	212:25-213:04	LC, O, NARR, R, 403		
Malani, Nirav	213:06-213:25	LC, O, NARR, R, 403		
Malani, Nirav	220:22-220:25			
Malani, Nirav	221:08-221:19			
Malani, Nirav	222:10-222:12			
Malani, Nirav	222:15-222:18	O, SPEC, V, R, 403		
Malani, Nirav	222:21-223:06	O, SPEC, V, R, 403		
Malani, Nirav	223:10-223:14	I, O, SPEC, V, R, 403		
Malani, Nirav		I, O, SPEC, V, R, 403		
Malani, Nirav		OB, AA, ARG, CP, F, I, LC, MIS, NARR, O, R,		
·		SPEC, 403, V		
Malani, Nirav	225:12-225:15	O, SPEC, V, R, 403		
Malani, Nirav		O, SPEC, V, R, 403		
Malani, Nirav		O, SPEC, V, R, 403		
Malani, Nirav		O, SPEC, V, R, 403		
Malani, Nirav	234:12-234:14	0, 31 20, 1, 1, 403		
Malani, Nirav		O, PK, SPEC, V, R, 403		
Malani, Nirav		O, PK, SPEC, V, R, 403		
Malani, Nirav	236:20-236:22		+	
Malani, Nirav		PK, SPEC, V, R, 403		
•			+	
Malani, Nirav		PK, SPEC, V, R, 403	+	
Malani, Nirav		PK, SPEC, V, R, 403	+	
Malani, Nirav		PK, SPEC, V, R, 403		
Malani, Nirav		PK, SPEC, V, R, 403		
Malani, Nirav	238:25-239:04	E NARR CREC V. R. 403	+	
Malani, Nirav		F, NARR, SPEC, V, R, 403	100.00.05.101.0.5	
Malani, Nirav		F, NARR, SPEC, V, R, 403	183:22-25; 184:3-6	H, BSD
Malani, Nirav		F, NARR, SPEC, V, R, 403	183:22-25; 184:3-6	H, BSD
Malani, Nirav	242:14-242:24			
Malani, Nirav		NARR, SPEC, V, R, 403		
Malani, Nirav	248:21-249:13	NARR, SPEC, V, R, 403		
Malani, Nirav	249:15-249:20	NARR, SPEC, V, R, 403		
Malani, Nirav	249:22-250:10	NARR, SPEC, V, R, 403		
Malani, Nirav	250:12-250:21	NARR, SPEC, V, R, 403		
Malani, Nirav	269:19-269:21			
	270:05-270:06			

	T		T	
Witness	Natera	Labcorp	Labcorp Counter-Designations	Natera Objections
	Designations	Objections		
Masukawa, Kevin	006:07-006:10			
Masukawa, Kevin	013:13-013:20			
Masukawa, Kevin	014:10-014:12			
Masukawa, Kevin	014:14-014:19			
Masukawa, Kevin	015:11-016:10			
Masukawa, Kevin	018:06-019:05			
Masukawa, Kevin	021:04-022:14	R, 403		
Masukawa, Kevin	022:21-023:10			
Masukawa, Kevin	023:13-024:15			
Masukawa, Kevin	024:19-025:05			
Masukawa, Kevin	025:10-026:11			
Masukawa, Kevin	027:19-028:24	ОВ		
Masukawa, Kevin	030:21-031:01			
Masukawa, Kevin	031:07-032:02			
Masukawa, Kevin	032:13-032:16		32:25-33:10	F, I
Masukawa, Kevin	032:22-032:24		32:25-33:10	F, I
Masukawa, Kevin	034:24-025:02			
Masukawa, Kevin	035:09-035:10		49:4-6; 49:9-19	MIS, F, I
Masukawa, Kevin	035:12-036:02		49:4-6; 49:9-19	MIS, F, I
Masukawa, Kevin	036:12-041:09	403, R	49:4-6; 49:9-19	MIS, F, I
Masukawa, Kevin	041:14-041:15			
Masukawa, Kevin	041:17-041:18			
Masukawa, Kevin	042:04-042:19			
Masukawa, Kevin	042:22-043:09			
Masukawa, Kevin	043:12-043:14			
Masukawa, Kevin	044:06-044:17			
Masukawa, Kevin	044:199-044:22			
Masukawa, Kevin	046:02-046:13			
Masukawa, Kevin	047:12-047:14			
Masukawa, Kevin	047:17-047:25			
Masukawa, Kevin	053:22-053:24		52:17-25; 53:3-18; 55:13-16	BSD, F, I, SPEC, V
Masukawa, Kevin	054:08-054:13		52:17-25; 53:3-18; 55:13-16	BSD, F, I, SPEC, V
Masukawa, Kevin	054:22-055:03		52:17-25; 53:3-18; 55:13-16	BSD, F, I, SPEC, V
Masukawa, Kevin	056:05-056:07		55:13-16	BSD, F, I, SPEC, V
Masukawa, Kevin	057:08-057:15		57:21-23; 59:9-15	BSD, F, I, SPEC, V
Masukawa, Kevin	058:03-058:07		57:21-23; 59:9-15	BSD, F, I, V
Masukawa, Kevin		R, 403, V, SPEC	62:14-16; 62:19-20	BSD, F, I, V
Masukawa, Kevin	063:14-063:21	N, 403, V, 3FEC	63:5-13	B3D, F, I, V
Masukawa, Kevin	064:04-064:16		65:23-66:17	E D V
Masukawa, Kevin	064:21-065:16		65:23-66:17	F, R, V BSD, F, R, V
Masukawa, Kevin	065:18-065:22		65:23-66:17	
				BSD, F, R, V
Masukawa, Kevin	068:23-069:04		68:4-7	BSD, F, R, V
Masukawa, Kevin	069:23-070:14		74 44 42 74 45 24	252.5.1.2.1/
Masukawa, Kevin	070:17-071:10		71:11-13; 71:15-24	BSD, F, I, R, V
Masukawa, Kevin	071:25-072:02			
Masukawa, Kevin	072:05-072:25			
Masukawa, Kevin	073:03-073:04			
Masukawa, Kevin	073:07-073:17		76:2.44. 77:40.42	DTC DCD 5 1 6555 ::
Masukawa, Kevin	075:18-076:02		76:3-14; 77:10-12	BTS, BSD, F, I, SPEC, V
Masukawa, Kevin	076:15-077:09	U	76:3-14; 77:10-12	BTS, BSD, F, I, SPEC, V
Masukawa, Kevin	078:02-079:02	0.04.60-5	79:3-5; 79:7-13; 80:8-10; 80:19-81:13; 81:15-22	BTS, BSD, F, I, R, SPEC, V
Masukawa, Kevin	079:14-080:07	O, PK, SPEC	79:3-5; 79:7-13; 80:8-10; 80:19-81:13; 81:15-22	BTS, BSD, F, I, R, SPEC, V
Masukawa, Kevin	080:11-080:13		79:3-5; 79:7-13; 80:8-10; 80:19-81:13; 81:15-22	BTS, BSD, F, I, R, SPEC, V
Masukawa, Kevin	080:16-080:18		79:3-5; 79:7-13; 80:8-10; 80:19-81:13; 81:15-22	BTS, BSD, F, I, R, SPEC, V
Masukawa, Kevin	082:11-083:09			
Masukawa, Kevin	083:15-083:23		83:24-25; 84:3-7; 84:18-85:5; 85:11-86:10; 87:2-25	BTS, BSD, F, I, R, SPEC, 403, V
Masukawa, Kevin	084:08-084:17	0	83:24-25; 84:3-7; 84:18-85:5; 85:11-86:10; 87:2-25	BTS, BSD, F, I, R, SPEC, 403, V
Masukawa, Kevin	085:06-085:07		83:24-25; 84:3-7; 84:18-85:5; 85:11-86:10; 87:2-25	BTS, BSD, F, I, R, SPEC, 403, V
Masukawa, Kevin	085:10-085:10		83:24-25; 84:3-7; 84:18-85:5; 85:11-86:10; 87:2-25	BTS, BSD, F, I, R, SPEC, 403, V
Masukawa, Kevin	086:11-086:14		83:24-25; 84:3-7; 84:18-85:5; 85:11-86:10; 87:2-25	BTS, BSD, F, I, R, SPEC, 403, V
Masukawa, Kevin	086:17-087:01		83:24-25; 84:3-7; 84:18-85:5; 85:11-86:10; 87:2-25	BTS, BSD, F, I, R, SPEC, 403, V
Masukawa, Kevin	088:21-089:13			
Masukawa, Kevin	089:16-090:09			
Masukawa, Kevin	090:11-091:15	R, 403	91:16-21; 92:1-2; 92:5	BTS, BSD, F, I, R, 403, V
Masukawa, Kevin	092:12-092:18	PK, SPEC	91:16-21; 92:1-2; 92:5	BTS, BSD, F, I, R, 403, V
Masukawa, Kevin	092:21-093:04		94:4-95:3; 96:8-17	BSD, F, I, R, 403, V
Masukawa, Kevin	093:07-093:22		94:4-95:3; 96:8-17	BSD, F, I, R, 403, V
Masukawa, Kevin	095:04-096:07	PK, SPEC	94:4-95:3; 96:8-17	BSD, F, I, R, 403, V
		· · ·		, , , ,,

Witness Natera		Labcorp	Labcorp Counter-Designations	Natera Objections
	Designations	Objections		
Masukawa, Kevin	096:18-096:20	PK, SPEC, O		
Masukawa, Kevin	096:23-100:23	PK, SPEC, O	101:18-21; 102:10-103:16; 103:19-23	BSD, F, I, MIS, SPEC, V
Masukawa, Kevin	103:24-104:14	PK, SPEC, O	101:18-21; 102:10-103:16; 103:19-23	BSD, F, I, MIS, SPEC, V
Masukawa, Kevin	116:08-116:11			
Masukawa, Kevin	116:18-116:20		117:3-13; 118:11-15	BSD, F, I
Masukawa, Kevin	116:22-117:02		117:3-13; 118:11-15	BSD, F, I
Masukawa, Kevin	117:14-117:18		117:3-13; 118:11-15	BSD, F, I
Masukawa, Kevin	118:23-118:23	I		
Masukawa, Kevin	119:03-119:19		120:5-121:10; 121:15-19	BSD, F, I
Masukawa, Kevin	121:11-121:14		120:5-121:10; 121:15-19; 123:15-16; 123:21-124:10	BSD, AA, F, I, V
Masukawa, Kevin	121:21-122:14		120:5-121:10; 121:15-19; 123:15-16; 123:21-124:10	BSD, AA, F, I, V
Masukawa, Kevin	122:17-122:19		120:5-121:10; 121:15-19; 123:15-16; 123:21-124:10	BSD, AA, F, I, V
Masukawa, Kevin	130:24-131:03		129:19-23; 129:25-130:18; 130:24-131:5; 131:9-17; 131:19-20	BSD, F, MIS, SPEC, V
Masukawa, Kevin	137:17-137:22			
Masukawa, Kevin	138:06-138:07		138:19-21; 138:24-139:3; 139:11-13; 139:20-24; 139:25-140:15	BSD, F, R, SPEC
Masukawa, Kevin	138:09-138:18		138:19-21; 138:24-139:3; 139:11-13; 139:20-24; 139:25-140:15	BSD, F, R, SPEC
Masukawa, Kevin	143:16-143:23			
Masukawa, Kevin	143:23-144:14			
Masukawa, Kevin	145:15-145:18			
Masukawa, Kevin	146:01-146:12		146:13-147:03	BSD, F, I
Masukawa, Kevin	148:23-023:25	SPEC, PK, O	148:16-18; 148:21-22	BSD, F, I
Masukawa, Kevin	149:03-150:11	SPEC, PK, O, F	148:16-18; 148:21-22	BSD, F, I
Masukawa, Kevin	150:14-153:03	SPEC, PK, O, F		
Masukawa, Kevin	153:05-153:08		153:16-22; 154:1-6; 154:10-14: 154:18-155:11; 155:14-15	BSD, BTS, F, I, MIS, R, SPEC
Masukawa, Kevin	153:12-153:15		153:16-22; 154:1-6; 154:10-14: 154:18-155:11; 155:14-15	BSD, BTS, F, I, MIS, R, SPEC
Masukawa, Kevin	156:12-157:21			
Masukawa, Kevin	157:23-158:02			
Masukawa, Kevin	159:23-161:09	R, 403		
Masukawa, Kevin	161:12-165:03			
Masukawa, Kevin	165:06-165:19	R, 403		

Witness	Natera	Labcorp Objections	Labcorp Counter-Designations	Natera
	Designations			Objections
Moyal, Hila	007:20-008:18			
Moyal, Hila	009:24-011:02			
Moyal, Hila	011:06-012:13			
Moyal, Hila	012:20-014:03			
Moyal, Hila		R, 403, BTS, PK, SPEC	249:2-251:7	BSD, H, L
Moyal, Hila		R, 403, BTS, PK, SPEC	249:2-251:7	BSD, H, L
Moyal, Hila	019:14-020:18		249:2-251:7	BSD, H, L
Moyal, Hila		R, 403, BTS, PK, SPEC	249:2-251:7	BSD, H, L
Moyal, Hila	_	R, 403, BTS, PK, SPEC R, 403, BTS, PK, SPEC	249:2-251:7	BSD, H, L
Moyal, Hila		R, 403, BTS, PK, SPEC	249:2-251:7	BSD, H, L
Moyal, Hila Moyal, Hila	+		249:2-251:7	BSD, H, L
Moyal, Hila		R, 403, BTS, PK, SPEC R, 403, BTS, PK, SPEC	249:2-251:7	BSD, H, L
Moyal, Hila	_	R, 403, BTS, PK, SPEC, F	249:2-251:7	BSD, H, L
Moyal, Hila		R, 403, BTS, PK, SPEC, F	249:2-251:7	BSD, H, L
Moyal, Hila		R, 403, BTS, PK, SPEC, F	245.2 251.7	030,11,1
Moyal, Hila		R, 403, BTS, PK, SPEC, F		
Moyal, Hila		R, 403, BTS, PK, SPEC, F		
Moyal, Hila		R, 403, BTS, PK, SPEC		
Moyal, Hila	_	R, 403, BTS, PK, SPEC		
Moyal, Hila	+	R, 403, BTS, PK, SPEC		
Moyal, Hila		R, 403, BTS, PK, SPEC		
Moyal, Hila		R, 403, BTS, PK, SPEC		
Moyal, Hila	045:18-047:01	R, 403, BTS, PK, SPEC, NARR		
Moyal, Hila	047:03-047:05	R, 403, BTS, PK, SPEC, NARR		
Moyal, Hila	047:12-047:15	R, 403, BTS, PK, SPEC, NARR		
Moyal, Hila		R, 403, BTS, PK, SPEC, NARR		
Moyal, Hila	048:20-049:13	R, 403, BTS, PK, SPEC, NARR, AA, V, CP		
Moyal, Hila	049:16-049:25	R, 403, I		
Moyal, Hila	050:08-051:07	R, 403, BTS, PK, SPEC		
Moyal, Hila	051:10-052:01	R, 403, BTS, PK, SPEC		
Moyal, Hila	052:03-052:12	R, 403, BTS, PK, SPEC		
Moyal, Hila		R, 403, BTS, PK, SPEC		
Moyal, Hila		R, 403, BTS, PK, SPEC		
Moyal, Hila		R, 403, BTS, PK, SPEC		
Moyal, Hila		R, 403, BTS, PK, SPEC, F		
Moyal, Hila		R, 403, BTS, PK, SPEC, F, AA		
Moyal, Hila		R, 403, BTS, PK, SPEC, F, AA		
Moyal, Hila Moyal, Hila		R, 403, BTS, PK, SPEC, F, AA R, 403, BTS, PK, SPEC, F, AA		
Moyal, Hila		R, 403, BTS, PK, SPEC, F, AA		
Moyal, Hila	060:01-061:10			
Moyal, Hila	061:13-062:10	n, 403, 1		
Moyal, Hila	062:12-063:09			
Moyal, Hila	063:22-064:17			
Moyal, Hila		R, 403, BTS, PK, SPEC, O, F, V		
Moyal, Hila		R, 403, BTS, PK, SPEC, O, F, V		
Moyal, Hila	067:14-068:24			
Moyal, Hila	069:01-069:02	I		
Moyal, Hila	069:07-069:14			
Moyal, Hila		R, 403, BTS, PK, SPEC, V		
Moyal, Hila		R, 403, BTS, PK, SPEC, V, I		
Moyal, Hila	075:15-075:16	R, 403, BTS, PK, SPEC, V, F		
Moyal, Hila		R, 403, BTS, PK, SPEC, V, F		
Moyal, Hila	075:23-077:08	R, 403, BTS, PK, SPEC, V, F		
Moyal, Hila	077:10-077:19	R, 403, BTS, PK, SPEC, V, F		
Moyal, Hila	078:10-078:18	R, 403, BTS, PK, SPEC, V, F, I		
Moyal, Hila	079:07-079:24	R, 403, BTS, PK, SPEC, I		
Moyal, Hila	080:15-081:05	R, 403, BTS, PK, SPEC		
Moyal, Hila		R, 403, BTS, V, AA		
Moyal, Hila		R, 403, BTS, V, AA		
Moyal, Hila		R, 403, BTS, V, PK, SPEC		
Moyal, Hila		R, 403, BTS, V, PK, SPEC	45:18-46:14; 249:2-251:7	BSD, H, L
Moyal, Hila		R, 403, BTS, V, PK, SPEC, NARR	45:18-46:14; 249:2-251:7	BSD, H, L
Moyal, Hila		R, 403, BTS, V, PK, SPEC, NARR	249:2-251:7	BSD, H, L
Moyal, Hila		R, 403, BTS, V, PK, SPEC	249:2-251:7	BSD, H, L
Moyal, Hila	091:15-093:04	R, 403, BTS, V, PK, SPEC	249:2-251:7	BSD, H, L

Witness	Natera	Labcorp Objections	Labcorp Counter-Designations	Natera
	Designations			Objections
Moyal, Hila		R, 403, BTS, V, PK, SPEC, MIS	249:2-251:7	BSD, H, L
Moyal, Hila	1	R, 403, BTS, V, PK, SPEC, MIS	249:2-251:7	BSD, H, L
Moyal, Hila	097:16-098:10			
Moyal, Hila	098:17-098:24			
Moyal, Hila	099:07-100:10			
Moyal, Hila		R, 403, BTS, V, PK, SPEC		
Moyal, Hila		R, 403, BTS, V, PK, SPEC		
Moyal, Hila		R, 403, BTS, V, PK, SPEC, NARR		
Moyal, Hila	1	R, 403, BTS, V, PK, SPEC, NARR		
Moyal, Hila		R, 403, BTS, V, PK, SPEC, NARR		
Moyal, Hila Moyal, Hila		R, 403, BTS, V, PK, SPEC, NARR		
Moyal, Hila		R, 403, BTS, V, PK, SPEC, NARR R, 403, BTS, V, PK, SPEC, NARR		
Moyal, Hila		R, 403, BTS, V, PK, SPEC, NARR		
Moyal, Hila	104:11-106:06			
Moyal, Hila	106:08-106:15			
Moyal, Hila	107:02-107:19	11, 403, 1, 61		
Moyal, Hila	107:21-108:20	R. 403. AA		
Moyal, Hila	1	R, 403, BTS, PK, SPEC		
Moyal, Hila	112:16-112:23	, , , , , , , , , , , , , , , , , , , ,		
Moyal, Hila	112:25-113:18			
Moyal, Hila		R, 403, BTS, PK, SPEC, NARR, CP		
Moyal, Hila		R, 403, BTS, PK, SPEC, NARR, CP		
Moyal, Hila		R, 403, BTS, PK, SPEC		
Moyal, Hila	116:25-117:15	R, 403, BTS, PK, SPEC		
Moyal, Hila	117:17-118:20	R, 403, BTS, PK, SPEC		
Moyal, Hila	118:22-119:03	R, 403, BTS, PK, SPEC		
Moyal, Hila	119:05-119:05	R, 403, BTS, PK, SPEC, CP		
Moyal, Hila	119:17-121:01	R, 403, BTS, PK, SPEC, CP		
Moyal, Hila	121:03-122:15	R, 403, BTS, PK, SPEC		
Moyal, Hila	123:05-123:09			
Moyal, Hila	123:13-125:09			
Moyal, Hila	125:11-125:21			
Moyal, Hila	126:03-129:11			
Moyal, Hila		R, 403, BTS, PK, SPEC, V		
Moyal, Hila	1	R, 403, BTS, PK, SPEC, V	249:2-251:7	BSD, H, L
Moyal, Hila	1	R, 403, BTS, PK, SPEC, V	249:2-251:7	BSD, H, L
Moyal, Hila	137:23-140:09		249:2-251:7	BSD, H, L
Moyal, Hila	141:01-142:06		240.2 251.7	DCD II I
Moyal, Hila	142:10-143:13		249:2-251:7	BSD, H, L
Moyal, Hila	143:17-144:05		249:2-251:7	BSD, H, L
Moyal, Hila Moyal, Hila	144:08-144:11 144:13-146:07		249:2-251:7 249:2-251:7	BSD, H, L BSD, H, L
Moyal, Hila	146:09-146:15		249:2-251:7	BSD, H, L
Moyal, Hila		R, 403, BTS, PK, SPEC, V	249:2-251:7	BSD, H, L
Moyal, Hila	1	R, 403, BTS, PK, SPEC, V, CP	243.2 231.7	555, 11, 2
Moyal, Hila		R, 403, BTS, PK, SPEC, V, CP		1
Moyal, Hila	152:05-153:09	,, ., 9, ., 5.		
Moyal, Hila		R, 403, BTS, PK, SPEC, V, CP, NARR		
Moyal, Hila	1	R, 403, BTS, PK, SPEC, V, CP, NARR		
Moyal, Hila	155:24-156:12			
Moyal, Hila	157:05-157:18			
Moyal, Hila	157:23-158:07			
Moyal, Hila	158:09-158:13	R, 403, BTS, PK, SPEC, V, CP	249:2-251:7	BSD, H, L
Moyal, Hila	158:16-161:20	R, 403, BTS, PK, SPEC, V, CP	249:2-251:7	BSD, H, L
Moyal, Hila	161:23-162:23		249:2-251:7	BSD, H, L
Moyal, Hila	164:01-165:17		249:2-251:7	BSD, H, L
Moyal, Hila	165:19-166:15	R, 403, BTS, PK, SPEC, V, MIS	249:2-251:7	BSD, H, L
Moyal, Hila		R, 403, BTS, PK, SPEC, V, MIS	249:2-251:7	BSD, H, L
Moyal, Hila	167:14-172:08		249:2-251:7	BSD, H, L
Moyal, Hila	172:23-173:04		249:2-251:7	BSD, H, L
Moyal, Hila	173:08-173:16		249:2-251:7	BSD, H, L
Moyal, Hila	173:19-173:24	i	174:25-175:2; 175:4-176:18; 176:20-25; 249:2-251:7	BSD, H, L, NR
Moyal, Hila		R, 403, BTS, PK, SPEC, MIS	174:25-175:2; 175:4-176:18; 176:20-25; 249:2-251:7	BSD, H, L, NR
Moyal, Hila		R, 403, BTS, PK, SPEC, MIS	174:25-175:2; 175:4-176:18; 176:20-25; 249:2-251:7	BSD, H, L, NR
Moyal, Hila		R, 403, BTS, PK, SPEC, MIS	174:25-175:2; 175:4-176:18; 176:20-25; 249:2-251:7	BSD, H, L, NR
Moyal, Hila	177:23-178:11	R, 403, BTS, PK, SPEC, MIS	174:25-175:2; 175:4-176:18; 176:20-25; 249:2-251:7	BSD, H, L, NR

Witness	Natera	Labcorp Objections	Labcorp Counter-Designations	Natera
	Designations			Objections
Moyal, Hila	178:13-178:16	R, 403, BTS, PK, SPEC, MIS	174:25-175:2; 175:4-176:18; 176:20-25; 249:2-251:7	BSD, H, L, NR
Moyal, Hila	179:10-179:22	R, 403, BTS, PK, SPEC, MIS	174:25-175:2; 175:4-176:18; 176:20-25; 249:2-251:7	BSD, H, L, NR
Moyal, Hila	180:06-180:25	1		
Moyal, Hila	181:02-183:15		249:2-251:7	BSD, H, L
Moyal, Hila	183:23-188:11		249:2-251:7	BSD, H, L
Moyal, Hila	189:13-191:25			
Moyal, Hila	192:03-192:13			
Moyal, Hila	192:16-195:12		249:2-251:7	BSD, H, L
Moyal, Hila	196:02-197:25	I, ARG, MIS, SPEC, R, 403	249:2-251:7	BSD, H, L
Moyal, Hila	198:14-199:01		249:2-251:7	BSD, H, L
Moyal, Hila	199:12-200:10			
Moyal, Hila	200:13-201:02			
Moyal, Hila	201:12-203:12	R, 403, BTS, PK, SPEC	249:2-251:7	BSD, H, L
Moyal, Hila	203:13-203:16	R, 403, BTS, PK, SPEC, AA	249:2-251:7	BSD, H, L
Moyal, Hila	203:20-204:03	R, 403, BTS, PK, SPEC	249:2-251:7	BSD, H, L
Moyal, Hila	204:05-204:15	R, 403, BTS, PK, SPEC, ARG	249:2-251:7	BSD, H, L
Moyal, Hila	205:05-206:06	R, 403, BTS, PK, SPEC, IH, MIS	249:2-251:7	BSD, H, L
Moyal, Hila	206:13-207:05	R, 403, BTS, PK, SPEC, V, IH	249:2-251:7	BSD, H, L
Moyal, Hila	207:07-207:12	R, 403, BTS, PK, SPEC, V		
Moyal, Hila	207:14-207:23	R, 403, BTS, PK, SPEC, V		
Moyal, Hila	208:01-208:08	R, 403, BTS, PK, SPEC, V		
Moyal, Hila	208:10-209:01			
Moyal, Hila	209:19-210:19	R, 403, BTS, SPEC, MIS, V, AA		
Moyal, Hila	211:15-214:01			
Moyal, Hila	214:11-217:13			
Moyal, Hila	217:16-218:07	R, 403, BTS, PK, SPEC, V		
Moyal, Hila	218:09-218:19	R, 403, BTS, PK, SPEC, V		
Moyal, Hila	218:23-219:06	R, 403, BTS, PK, SPEC, V, MIS, AA		
Moyal, Hila	219:08-223:22		249:2-251:7	BSD, H, L
Moyal, Hila	223:24-228:17	R, 403, BTS, PK, SPEC, V, MIS	249:2-251:7	BSD, H, L
Moyal, Hila	228:19-229:08	R, 403, BTS, PK, SPEC, V, MIS, P		
Moyal, Hila	230:01-230:05			
Moyal, Hila	230:12-230:19			
Moyal, Hila	231:06-233:13		249:2-251:7	BSD, H, L
Moyal, Hila	234:06-237:09	R, 403, BTS, PK, SPEC, V	249:2-251:7	BSD, H, L
Moyal, Hila	237:17-238:08	R, 403, BTS, PK, SPEC, V, O	249:2-251:7	BSD, H, L
Moyal, Hila	238:20-239:17	R, 403, BTS, PK, SPEC, V, O	249:2-251:7	BSD, H, L
Moyal, Hila	239:22-240:04	R, 403, BTS, PK, SPEC, V, O	249:2-251:7	BSD, H, L
Moyal, Hila	240:06-240:15	R, 403, BTS, PK, SPEC, V, O, ARG, AA	249:2-251:7	BSD, H, L
Moyal, Hila	241:03-241:08	AA	249:2-251:7	BSD, H, L
Moyal, Hila	241:23-243:10		249:2-251:7	BSD, H, L
Moyal, Hila	244:04-244:24	R, 403, BTS, PK, SPEC, V		
Moyal, Hila		R, 403, BTS, PK, SPEC, V		
Moyal, Hila	247:19-247:24	R, 403		
Moyal, Hila	252:10-257:21	R, 403, BTS, PK, SPEC, V, AA, O, ARG	249:2-251:7	BSD, H, L

Olivares, Eric Olivares, Eric	Designations			
-				
Olivares, Eric	010:09-010:21			
	011:14-012:01			
Olivares, Eric	012:05-012:07			
Olivares, Eric	012:16-013:15			
Olivares, Eric	013:21-014:07			
Olivares, Eric	014:09-014:24			
Olivares, Eric	015:06-016:16			
Olivares, Eric	016:20-017:05			
Olivares, Eric	020:23-022:23			
Olivares, Eric Olivares, Eric	023:02-025:24 028:10-028:18			
Olivares, Eric	029:06-029:19			+
Olivares, Eric		R, 403, PK, SPEC, CP, I, H		
Olivares, Eric	034:20-034:24	11, 403, 1 K, 31 LC, CI , I, II		
Olivares, Eric		R, 403, PK, SPEC, CP, H		
Olivares, Eric		R, 403, PK, SPEC, CP, H		
Olivares, Eric		R, 403, PK, SPEC, CP, H, V		
Olivares, Eric		R, 403, PK, SPEC, CP, H, V		
Olivares, Eric		R, 403, CP, H, V		1
Olivares, Eric		R, 403, CP, H, V		
Olivares, Eric	039:09-040:25	R, 403, CP, H, V, I		
Olivares, Eric	041:06-041:06	R, 403, CP, H, V, I		
Olivares, Eric	041:10-042:05	Н		
Olivares, Eric	042:08-043:05	н		
Olivares, Eric	044:05-044:18	Н		
Olivares, Eric	045:12-045:20			
Olivares, Eric	046:12-046:17			
Olivares, Eric		R, 403, V, H, PK, SPEC, CP	49:11-12; 49:14	BSD, H
Olivares, Eric		R, 403, V, H, PK, SPEC, CP	49:11-12; 49:14	BSD, H
Olivares, Eric		R, 403, V, H, PK, SPEC, CP	49:11-12; 49:14	BSD, H
Olivares, Eric		R, 403, V, H, PK, SPEC, CP	49:11-12; 49:14	BSD, H
Olivares, Eric		R, 403, V, H, PK, SPEC, CP		
Olivares, Eric Olivares, Eric		R, 403, V, H, PK, SPEC, CP, NARR R, 403, V, H, PK, SPEC, CP, NARR		+
Olivares, Eric		R, 403, V, H, PK, SPEC, O		+
Olivares, Eric	053:10-053:19			
Olivares, Eric		R, 403, V, H, PK, SPEC		
Olivares, Eric		R, 403, V, H, PK, SPEC		
Olivares, Eric		R, 403, V, H, PK, SPEC, O		
Olivares, Eric		R, 403, V, H, PK, SPEC		
Olivares, Eric		R, 403, V, H, PK, SPEC		
Olivares, Eric	056:18-057:08			
Olivares, Eric	057:23-057:25	R, 403, V, H, PK, SPEC		
Olivares, Eric	058:02-058:05	R, 403, V, H, PK, SPEC		
Olivares, Eric	058:16-058:18	R, 403, V, H, PK, SPEC		
Olivares, Eric	058:20-060:06	R, 403, V, H, PK, SPEC		
Olivares, Eric	060:23-061:13	R, 403, V, H, PK, SPEC, NARR, MIS		
Olivares, Eric	061:15-061:20	R, 403, V, H, PK, SPEC, NARR, MIS		
Olivares, Eric		R, 403, V, H, PK, SPEC		
Olivares, Eric		R, 403, V, H, PK, SPEC		
Olivares, Eric		R, 403, V, H, PK, SPEC		
Olivares, Eric		R, 403, V, H, PK, SPEC, IH		
Olivares, Eric		R, 403, V, H, PK, SPEC, IH		
Olivares, Eric	066:24-066:25			+
Olivares, Eric	067:10-067:11	D 403 V II CD50 DV V		+
Olivares, Eric		R, 403, V, H, SPEC, PK, V		+
Olivares, Eric		R, 403, V, H, SPEC, PK, V		+
Olivares, Eric		R, 403, V, H, SPEC, PK, V		+
Olivares, Eric	069:08-069:23	H B 403 // SBEC BV CB	71-4 0	DCD II
Olivares, Eric		H, R, 403, V, SPEC, PK, CP H, R, 403, V, SPEC, PK, CP	71:4-9 71:4-9	BSD, H
Olivares, Eric Olivares, Eric	070:17-070:19		/1.4-3	BSD, H
Ulivai CS, EIIC		R, 403, V, IH, SPEC, PK, CP		+

Witness	Natera	Labcorp Objections	Labcorp Counter-Designations	Natera Objections
	Designations			
Olivares, Eric		R, 403, V, IH, SPEC, PK, O		
Olivares, Eric		R, 403, V, IH, SPEC, PK, O		
Olivares, Eric		R, 403, V, IH, SPEC, PK, O	49:11-12; 49:14	BSD, H
Olivares, Eric		R, 403, V, IH, SPEC, PK, O	49:11-12; 49:14	BSD, H
Olivares, Eric	076:21-077:02		49:11-12; 49:14	BSD, H
Olivares, Eric	077:11-077:14		49:11-12; 49:14; 71:4-9; 77:15-17; 77:20-78:1	BSD, H
Olivares, Eric Olivares, Eric		R, 403, V, IH, SPEC, PK, O, NARR	77:15-17; 77:20-78:1	BSD, H
Olivares, Eric		403, V, IH, SPEC, PK, O, NARR, CP 403, V, IH, SPEC, PK, O, NARR, CP		
Olivares, Eric	082:06-082:10	11, 403, V, 111, 31 EC, 1 K, O, NAKK, CI		
Olivares, Eric	082:21-084:11	H. OB		
Olivares, Eric	084:22-085:13	,		
Olivares, Eric	085:16-085:25			
Olivares, Eric		R, 403, V, IH, SPEC, PK, O, NARR, CP, H	49:11-12; 49:14	BSD, H
Olivares, Eric		R, 403, V, IH, SPEC, PK, O, NARR, CP, H	49:11-12; 49:14	BSD, H
Olivares, Eric	089:16-090:22	R, 403, SPEC, PK, H	·	
Olivares, Eric	090:24-091:24	R, 403, SPEC, PK, H		
Olivares, Eric		R, 403, SPEC, PK, H		
Olivares, Eric	093:16-093:21			
Olivares, Eric		R, 403, SPEC, PK, H	49:11-12; 49:14	BSD, H
Olivares, Eric		R, 403, SPEC, PK, H, O		
Olivares, Eric	+	R, 403, SPEC, PK, H, O		
Olivares, Eric	099:18-100:03			
Olivares, Eric	100:07-100:10			
Olivares, Eric	100:13-101:09			
Olivares, Eric		R, 403, SPEC, PK, O, H	49:11-12; 49:14	BSD, H
Olivares, Eric		R, 403, SPEC, PK, H	49:11-12; 49:14	BSD, H
Olivares, Eric		R, 403, SPEC, PK, H, V, IH	49:11-12; 49:14	BSD, H
Olivares, Eric	109:05-109:09		40.11 12. 40.14. 71.4 0	DCD II
Olivares, Eric Olivares, Eric		R, 403, SPEC, PK, H, V, AA R, 403, SPEC, PK, H, V, AA	49:11-12; 49:14; 71:4-9	BSD, H BSD, H
Olivares, Eric		R, 403, SPEC, PK, H, V	49:11-12; 49:14; 71:4-9 49:11-12; 49:14	BSD, H
Olivares, Eric		R, 403, SPEC, PK, H, V	49:11-12; 49:14	BSD, H
Olivares, Eric		R, 403, SPEC, PK, H, CP, F	49:11-12; 49:14	BSD, H
Olivares, Eric	115:08-117:06		49:11-12; 49:14	BSD, H
Olivares, Eric		R, 403, SPEC, PK, H	49:11-12; 49:14	BSD, H
Olivares, Eric		R, 403, SPEC, PK, H, AA	49:11-12; 49:14	BSD, H
Olivares, Eric	119:24-122:18	H	49:11-12; 49:14	BSD, H
Olivares, Eric	122:21-123:03	R, 403, SPEC, PK, H, O, IH		
Olivares, Eric	123:05-125:14	R, 403, SPEC, PK, H, O, IH		
Olivares, Eric	125:22-126:25	Н		
Olivares, Eric	127:06-129:13	Н		
Olivares, Eric	129:23-131:05	R, 403, SPEC, PK, AA, H		
Olivares, Eric		R, 403, SPEC, PK, AA, H		
Olivares, Eric	132:03-132:19			
Olivares, Eric	132:23-133:06			
Olivares, Eric	133:08-133:18			
Olivares, Eric	133:25-134:25			
Olivares, Eric		R, 403, SPEC, PK, H		
Olivares, Eric	136:01-136:01	·	40·11 12· 40·14· 71·4 0	Вси п
Olivares, Eric Olivares, Eric	136:15-137:24 138:01-138:08		49:11-12; 49:14; 71:4-9 49:11-12; 49:14; 71:4-9	BSD, H BSD, H
Olivares, Eric		R, 403, SPEC, PK, H	49:11-12; 49:14; 71:4-9	BSD, H
Olivares, Eric	144:01-136:13			555,11
Olivares, Eric	146:21-148:14			
Olivares, Eric		R, 403, SPEC, PK, V, H	149:25-150:9	Н
Olivares, Eric		R, 403, SPEC, PK, V, H	149:25-150:9	Н
Olivares, Eric		R, 403, SPEC, PK, V, H	149:25-150:9	Н
Olivares, Eric	1	R, 403, SPEC, PK, V, H		
Olivares, Eric	151:08-152:14	1		
Olivares, Eric	152:23-153:10			
Olivares, Eric	153:21-154:02			
Olivares, Eric	154:13-154:18	Н		

Witness	Natera	Labcorp Objections	Labcorp Counter-Designations	Natera Objections
	Designations			
Olivares, Eric	155:02-156:12	Н		
Olivares, Eric	156:18-158:14			
Olivares, Eric	158:21-161:10			
Olivares, Eric		R, 403, PK, SPEC, H		
Olivares, Eric	162:11-163:18	R, 403, PK, SPEC, H		
Olivares, Eric	163:21-164:15			
Olivares, Eric	164:17-165:20			
Olivares, Eric	167:03-167:08	R, 403, V, H, SPEC, PK		
Olivares, Eric		R, 403, V, H, SPEC, PK		
Olivares, Eric	171:01-171:22			
Olivares, Eric	171:24-175:24			
Olivares, Eric	177:08-179:07			
Olivares, Eric	180:05-183:03			
Olivares, Eric	183:08-184:04	R, 403, H, SPEC, PK		
Olivares, Eric	184:07-184:14	R, 403, H, SPEC, PK		
Olivares, Eric		R, 403, H, SPEC, PK		
Olivares, Eric		R, 403, H, SPEC, PK		
Olivares, Eric		R, 403, H, SPEC, PK		
Olivares, Eric	186:22-187:05			
Olivares, Eric	188:09-190:01			
Olivares, Eric	190:11-190:21			
Olivares, Eric	191:12-192:23			
Olivares, Eric	192:25-195:09	R, 403, H, SPEC, PK		
Olivares, Eric	195:11-195:11	R, 403, H, SPEC, PK		
Olivares, Eric	195:24-196:14	R, 403, H, SPEC, PK		
Olivares, Eric	198:08-200:09			
Olivares, Eric		R, 403, H, SPEC, PK		
Olivares, Eric		R, 403, H, SPEC, PK		
Olivares, Eric		R, 403, H, SPEC, PK		
Olivares, Eric		R, 403, H, SPEC, PK		
Olivares, Eric		R, 403, H, SPEC, PK		
Olivares, Eric		R, 403, H, SPEC, PK		
Olivares, Eric		R, 403, H, SPEC, PK		
Olivares, Eric	206:19-208:07			
Olivares, Eric		R, 403, H, SPEC, PK		
Olivares, Eric		R, 403, H, SPEC, PK		
Olivares, Eric	212:09-214:04			
Olivares, Eric		R, 403, H, SPEC, PK, MIS		
Olivares, Eric		R, 403, H, SPEC, PK, MIS		
Olivares, Eric		R, 403, H, SPEC, PK, V, CP		
Olivares, Eric		R, 403, H, SPEC, PK, V, CP		
Olivares, Eric		R, 403, H, SPEC, PK, V, CP		
Olivares, Eric		R, 403, H, SPEC, PK, V, CP		
Olivares, Eric		R, 403, H, SPEC, PK, V, CP		
Olivares, Eric		R, 403, H, SPEC, PK, V, CP		
Olivares, Eric		R, 403, H, SPEC, PK, V, CP		
Olivares, Eric		R, 403, H, SPEC, PK, V, CP		
Olivares, Eric		R, 403, H, SPEC, PK, V, CP		
Olivares, Eric	230:07-230:16 230:25-232:04	ш		
Olivares, Eric				
Olivares, Eric	232:18-234:11			
Olivares, Eric Olivares, Eric		R, 403, H, SPEC, PK, V, CP, LC R, 403, H, SPEC, PK, V, CP, LC		
Olivares, Eric		R, 403, H, SPEC, PK, V, CP, LC		
Olivares, Eric		R, 403, H, SPEC, PK, V, CP, LC		
·				
Olivares, Eric		R, 403, H, SPEC, PK, V, CP, LC		
Olivares, Eric		R, 403, H, SPEC, PK, V, CP, LC		
Olivares, Eric		R, 403, H, SPEC, PK, V, CP, LC		
Olivares, Eric		R, 403, H, SPEC, PK, V, NARR		
Olivares, Eric		R, 403, H, SPEC, PK, V, NARR, ARG		
Olivares, Eric		R, 403, H, SPEC, PK, V, NARR, ARG		
Olivares, Eric		R, 403, H, SPEC, PK, V, CP		
Olivares, Eric	247:18-247:20	R, 403, H, SPEC, PK, V, CP		

Witness	Natera	Labcorp Objections	Labcorp Counter-Designations	Natera Objections
	Designations			
Olivares, Eric	248:09-249:05	Н		
Olivares, Eric	249:13-249:21	Н		
Olivares, Eric	249:23-253:13	Н		
Olivares, Eric	253:19-255:05	Н		
Olivares, Eric	255:13-256:10	Н		
Olivares, Eric	256:18-257:13			
Olivares, Eric	258:09-259:20	R, 403, SPEC, PK, H		
Olivares, Eric	260:04-260:12	R, 403, H, SPEC, PK		
Olivares, Eric	260:15-260:17	R, 403, H, SPEC, PK		
Olivares, Eric	261:06-261:22	R, 403, H, SPEC, PK	49:11-12; 49:14	BSD, H
Olivares, Eric	261:24-262:03	R, 403, H, SPEC, PK	49:11-12; 49:14	BSD, H
Olivares, Eric	262:06-262:06	R, 403, H, SPEC, PK	49:11-12; 49:14	BSD, H
Olivares, Eric		R, 403, H, SPEC, PK	49:11-12; 49:14	BSD, H
Olivares, Eric		R, 403, H, SPEC, PK	49:11-12; 49:14	BSD, H
Olivares, Eric	267:05-268:10	R, 403, H, SPEC, PK	49:11-12; 49:14	BSD, H
Olivares, Eric	268:21-271:04	Н		
Olivares, Eric	271:18-272:17	Н		
Olivares, Eric	273:01-274:23	R, 403, H, NARR		
Olivares, Eric	275:05-275:13			
Olivares, Eric	276:01-276:14	I		
Olivares, Eric	277:10-279:12	Н		
Olivares, Eric	279:17-279:25	R, 403, H, SPEC, PK		
Olivares, Eric	280:03-281:11			
Olivares, Eric	282:14-286:02	R, 403, H, SPEC, PK		
Olivares, Eric	286:05-286:19	R, 403, H, SPEC, PK		
Olivares, Eric	287:14-287:21	R, 403, H, SPEC, PK		
Olivares, Eric	288:03-288:03	R, 403, H, SPEC, PK		
Olivares, Eric	289:12-289:23	R, 403, H, PK		
Olivares, Eric	290:07-292:08			
Olivares, Eric	292:14-295:22	R, 403, H, SPEC, PK, O		
Olivares, Eric	295:24-297:04	R, 403, H, SPEC, PK, NARR, O		
Olivares, Eric	297:06-297:07	R, 403, H, SPEC, PK, NARR, O		
Olivares, Eric	297:11-297:24	R, 403, H, SPEC, PK, O		
Olivares, Eric	298:01-298:11	Н		
Olivares, Eric	298:20-299:14	Н		
Olivares, Eric	300:05-301:09	R, 403, H, MIS, SPEC, PK		
Olivares, Eric	301:15-302:02	R, 403, H, MIS, SPEC, PK		
Olivares, Eric	302:14-303:03			
Olivares, Eric	303:07-306:24	R, 403, H, MIS, SPEC, PK, O, LC, I, NARR		
Olivares, Eric	307:07-308:09	R, 403, H, MIS, SPEC, PK, O, LC, NARR		

Witness Natera Designations		Labcorp Objections	Labcorp Counter-Designations	Natera Objections	
aul, Joshua	010:11-010:18				
aul, Joshua	015:12-015:13				
aul, Joshua	015:18-015:19				
aul, Joshua	015:23-015:23				
aul, Joshua	016:03-017:02				
aul, Joshua	022:13-023:11				
aul, Joshua	023:24-024:20	R, 403, V, SPEC, PK, O	25:11-15	BSD, H	
aul, Joshua	025:19-026:11	R, 403, V, SPEC, PK	25:11-15	BSD. H	
aul, Joshua	028:12-028:21	R, 403, V, SPEC, PK	25:11-15	BSD, H	
aul. Joshua	028:23-028:24	R, 403, V, SPEC, PK	25:11-15	BSD, H	
aul, Joshua	029:02-029:16	R, 403, V, SPEC, BTS	25:11-15	BSD, H	
aul, Joshua	029:18-029:20	R, 403, V, SPEC, BTS	25:11-15	BSD, H	
aul, Joshua	029:22-030:03	R, 403, V, SPEC, BTS	25:11-15	BSD, H	
aul, Joshua	030:16-032:01	11, 103, 1,31 25, 513	23.11 13	555,11	
aul, Joshua	033:03-033:16				
aul, Joshua	037:09-037:10	R, 403, V, SPEC, BTS, CP			
aul, Joshua	037:23-037:20	R, 403, V, SPEC, BTS, CP, I			
aul, Joshua aul, Joshua	037:23-037:20	11, 400, V, 31 LC, D13, CF, I	25:11-15	BSD, H	
aul, Joshua aul, Joshua	038:13-038:24	R, 403, V, SPEC, BTS, CP, MIS	25:11-15 25:11-15; 40:18-41:11	BSD, H	
aul, Joshua aul, Joshua	040:14-040:16	R, 403, V, SPEC, BTS, CP, MIS	25:11-15; 40:18-41:11 25:11-15; 40:18-41:11	BSD, H	
aul, Joshua aul, Joshua	043:12-043:17	R, 403, V, SPEC, BTS, CP, MIS, F	ZJ.11-1J, 4U.10-41.11	, חכט, ח	
aul, Joshua aul, Joshua	043:12-043:17				
,	+	R, 403, SPEC, BTS, CP, MIS, F			
aul, Joshua	044:16-044:17				
aul, Joshua	044:20-045:04				
aul, Joshua	045:10-045:19				
aul, Joshua	046:01-046:10				
aul, Joshua	047:12-047:14				
aul, Joshua	047:22-047:23				
aul, Joshua	048:06-048:13		48:22-25	Н	
aul, Joshua	051:05-051:20				
aul, Joshua	052:07-052:10	R, 403, V, PK, SPEC			
aul, Joshua	052:17-052:22	R, 403, V, BTS			
aul, Joshua	052:24-052:24	R, 403, V, BTS			
aul, Joshua	053:02-053:03	R, 403, V, BTS, PK, SPEC			
aul, Joshua	053:05-053:05	R, 403, V, BTS, PK, SPEC			
aul, Joshua	053:07-053:08	R, 403, V, BTS, PK, SPEC			
aul, Joshua	053:10-053:12	R, 403, V, BTS, PK, SPEC			
aul, Joshua	053:14-053:16	R, 403, BTS			
aul, Joshua	054:06-054:09	R, 403, BTS, V	54:14-25	BSD, H, I	
aul, Joshua	054:11-054:12	R, 403, BTS, V	54:14-25	BSD, H, I	
aul, Joshua	057:21-058:01	R, 403, BTS, PK, SPEC, F, O			
aul, Joshua	058:03-058:08	R, 403, BTS, PK, SPEC, F, O			
aul, Joshua	058:10-058:12	R, 403, BTS, PK, SPEC, F	58:17-59:14	BSD, H	
aul, Joshua	058:14-058:14	R, 403, BTS, PK, SPEC, F	58:17-59:14	BSD, H	
aul, Joshua	061:22-062:05				
aul, Joshua	063:04-063:06				
aul, Joshua	063:23-063:25	R, 403, BTS, PK, SPEC, F, O			
aul, Joshua	064:02-064:03	R, 403, BTS, PK, SPEC, F, O			
aul, Joshua	066:21-067:03	R, 403, BTS, PK, SPEC, F, O	25:11-15; 48:22-25; 65:21-23; 65:25-66:6; 68:5-8; 68:10-19	BSD, H	
Paul, Joshua	067:06-067:10	R, 403, BTS, PK, SPEC, F, O	25:11-15; 48:22-25; 65:21-23; 65:25-66:6; 68:5-8; 68:10-19	BSD, H	
aul, Joshua	067:20-067:24	R, 403, BTS, PK, SPEC, F, O	25:11-15; 48:22-25; 65:21-23; 65:25-66:6; 68:5-8; 68:10-19	BSD, H	
aul, Joshua	068:01-068:03	R, 403, BTS, PK, SPEC, F, O	25:11-15; 48:22-25; 65:21-23; 65:25-66:6; 68:5-8; 68:10-19	BSD, H	
aul, Joshua	069:04-069:10	R, 403, BTS, PK, SPEC, F, O	25:11-15; 48:22-25; 65:21-23; 65:25-66:6; 68:5-8; 68:10-19; 69-17-20; 69:22-25	BSD, H	
Paul, Joshua	069:13-069:15	R, 403, BTS, PK, SPEC, F, O	25:11-15; 48:22-25; 65:21-23; 65:25-66:6; 68:5-8; 68:10-19; 69-17-20; 69:22-25	BSD, H	
aul, Joshua	072:05-072:06	R, 403, BTS, PK, SPEC, F, O, LC, V, NARR	25:11-15; 48:22-25; 65:21-23; 65:25-66:6; 68:5-8; 68:10-19; 69-17-20; 69:22-25	BSD, H	

Witness	Natera Designations	Labcorp Objections	Labcorp Counter-Designations	Natera Objections	
Paul, Joshua	072:12-072:14	R, 403, BTS, PK, SPEC, F, O, LC, V, NARR	25:11-15; 48:22-25; 65:21-23; 65:25-66:6; 68:5-8; 68:10-19; 69-17-20; 69:22-25	BSD, H	
Paul, Joshua	076:05-076:11	R, 403, BTS, SPEC, LC, V			
Paul, Joshua	076:14-076:14	R, 403, BTS, SPEC, LC, V			
Paul, Joshua	076:17-076:23	R, 403, BTS, PK, SPEC, LC, V			
Paul, Joshua	076:25-076:25	R, 403, BTS, PK, SPEC, V			
Paul, Joshua	087:03-087:04	R, 403, BTS, PK, SPEC, V			
Paul, Joshua	087:06-087:07	R, 403, BTS, PK, SPEC, V	R, 403, BTS, PK, SPEC, V		
Paul, Joshua	087:09-087:09	R, 403, BTS, PK, SPEC, V			
Paul, Joshua	087:11-087:15	R, 403, BTS, PK, SPEC, V, O			
Paul, Joshua	087:17-087:17	R, 403, BTS, PK, SPEC, V, O			
Paul, Joshua	087:19-087:21	R, 403, BTS, PK, SPEC, V, O			
Paul, Joshua	087:23-088:03				
Paul, Joshua	088:13-088:17	R, 403, BTS, V, NARR, CP			
Paul, Joshua	088:20-088:20				
Paul, Joshua	088:22-088:23	R, 403, BTS, V, NARR, PK, SPEC, O, LC	25:11-15; 89:3-20	BSD, H	
Paul, Joshua	089:01-089:02	R, 403, BTS, V, NARR, PK, SPEC, LC	25:11-15; 89:3-20	BSD, H	
Paul, Joshua	089:21-091:04	R, 403, BTS, V, NARR, PK, SPEC, O, LC	25:11-15; 89:3-20	BSD, H	
Paul, Joshua	091:06-091:08	R, 403, BTS, V, NARR, PK, SPEC, O, LC	25:11-15; 89:3-20	BSD, H	
Paul, Joshua	091:10-093:02	R, 403, BTS, V, NARR, PK, SPEC, O, LC	25:11-15; 89:3-20	BSD, H	
Paul, Joshua	093:10-093:11	D 403 V DTC DV CDEC E			
Paul, Joshua	093:20-094:02	R, 403, V, BTS, PK, SPEC, F			
Paul, Joshua Paul. Joshua	094:04-094:04	R, 403, V, BTS, PK, SPEC, F			
Paul, Joshua Paul, Joshua	094:06-095:04 096:03-096:04	R, 403, V, BTS, PK, SPEC, F R, 403, V, BTS, PK, SPEC, F	96:5-12	BSD, H	
Paul, Joshua	099:01-099:03	R, 403, V, BTS, PK, SPEC, F, LC, O	96:5-12; 99:8-9; 99:11-15; 99:17-18; 99:20-21	BSD, H	
Paul, Joshua	099:05-099:06	R, 403, V, BTS, PK, SPEC, F, LC, O	96:5-12; 99:8-9; 99:11-15; 99:17-18; 99:20-21	BSD, H	
Paul, Joshua	103:06-104:05	R, 403, V, BTS, SPEC	104:6-18	BSD, H	
Paul, Joshua	104:19-106:06	R, 403, V, BTS, SPEC, O	104:6-18	BSD, H	
Paul, Joshua	106:23-107:14	R, 403, V, BTS, SPEC, O	25:11-15	BSD, H	
Paul, Joshua	107:16-107:17	R, 403, V, BTS, SPEC, O	25:11-15; 108:19-21; 108:23-109:3	BSD, H	
Paul, Joshua	107:19-107:21	R, 403, V, BTS, SPEC, O	25:11-15; 108:19-21; 108:23-109:3	BSD, H	
Paul, Joshua	108:08-108:10	R, 403, V, BTS, SPEC, O	25:11-15; 108:19-21; 108:23-109:3	BSD, H	
Paul, Joshua	108:12-108:17	R, 403, V, BTS, SPEC, O	25:11-15; 108:19-21; 108:23-109:3	BSD, H	
Paul, Joshua	113:20-113:22	R, 403, V, BTS, SPEC, O	25:11-15; 108:19-21; 108:23-109:3; 112:15- 113:08	BSD, H	
Paul, Joshua	113:24-113:24	R, 403, V, BTS, SPEC, O, I	25:11-15; 108:19-21; 108:23-109:3; 112:15- 113:08	BSD, H	
Paul, Joshua	114:12-114:15	R, 403, V, BTS, SPEC, O	25:11-15; 108:19-21; 108:23-109:3; 112:15- 113:08	BSD, H	
Paul, Joshua	114:17-114:25	R, 403, V, BTS, SPEC, O	25:11-15; 108:19-21; 108:23-109:3; 112:15- 113:08	BSD, H	
Paul, Joshua	117:13-117:15	R, 403, V, BTS, SPEC, O, PK			
Paul, Joshua	117:18-117:25	R, 403, V, BTS, SPEC, O, PK			
Paul, Joshua	118:02-118:23	R, 403, V, BTS, SPEC, O, PK			
Paul, Joshua	119:22-120:15				
Paul, Joshua	121:17-122:08	R, 403, V, BTS, SPEC, O, PK			
Paul, Joshua	122:10-122:11	R, 403, V, BTS, SPEC, O, PK			
Paul, Joshua	122:13-122:21	R, 403, V, BTS, SPEC, O, PK			
Paul, Joshua	122:23-122:24	R, 403, V, BTS, SPEC, O, PK			
Paul, Joshua	123:02-123:12	R, 403, V, BTS, SPEC, O, PK			
Paul, Joshua	123:14-123:15	R, 403, V, BTS, SPEC, O, PK			
Paul, Joshua	123:17-123:18	R, 403, V, BTS, SPEC, O, PK			
Paul, Joshua	123:20-123:23	R, 403, V, BTS, SPEC, O, PK	125 12 15 125 17 126 2	202 11	
Paul, Joshua			125:12-15; 125:17-126:2	BSD, H	
Paul, Joshua	126:04-126:06	R, 403, V, BTS, SPEC, O, PK	125:12-15; 125:17-126:2	BSD, H	
Paul, Joshua	126:08-126:08	R, 403, V, BTS, SPEC, O, PK	125:12-15; 125:17-126:2	BSD, H	
Paul, Joshua	126:10-126:24	R, 403, V, BTS, SPEC, O, PK	125:12-15; 125:17-126:2	BSD, H	
Paul, Joshua Paul, Joshua	129:07-130:13 134:18-134:20	R, 403, V, BTS, SPEC, O, PK			

Witness	Natera Designations	Labcorp Objections	Labcorp Counter-Designations	Natera Objections
Paul, Joshua	135:09-135:10		135:11-12	Н
Paul, Joshua	135:13-136:07		135:11-12	Н
aul, Joshua	136:12-137:03	R, 403, SPEC, V	135:11-12	Н
aul, Joshua	137:21-138:12	R, 403, BTS, SPEC, V, O	139:18-20; 139:22-140:6	BSD, H
aul, Joshua	138:14-138:15	R, 403, BTS, SPEC, V, O	139:18-20; 139:22-140:6	BSD, H
aul, Joshua	138:17-138:18	R, 403, BTS, SPEC, V, O 139:18-20; 139:22-140:6		BSD, H
aul, Joshua	138:20-139:16	R, 403, BTS, SPEC, V, O	139:18-20; 139:22-140:6	BSD, H
Paul, Joshua	141:02-142:09	R, 403, BTS, SPEC, V, O	139:18-20; 139:22-140:6	BSD, H
Paul, Joshua	142:20-143:02	R, 403, BTS, PK, SPEC, V, O, CP	139:18-20; 139:22-140:6	BSD, H
Paul, Joshua	143:04-143:10	R, 403, BTS, PK, SPEC, V, O, CP	139:18-20; 139:22-140:6	BSD, H
Paul, Joshua	143:12-143:16	R, 403, BTS, PK, SPEC, V, O, CP	139:18-20; 139:22-140:6	BSD, H
Paul, Joshua	143:18-143:24	R, 403, BTS, PK, SPEC, V, O, CP	139:18-20; 139:22-140:6	BSD, H
Paul, Joshua	144:09-145:15	R, 403, BTS, PK, SPEC, V, O, CP		
Paul, Joshua	145:17-145:18	R, 403, BTS, PK, SPEC, V, O, CP		
Paul, Joshua	145:20-145:20	R, 403, BTS, PK, SPEC, V, O, CP		
Paul, Joshua	145:22-146:02	R, 403, BTS, PK, SPEC, V, O, CP		
Paul, Joshua	146:04-146:07	R, 403, BTS, PK, SPEC, V, O, CP		
Paul, Joshua	146:09-146:14	R, 403, BTS, PK, SPEC, V, O, CP		
Paul, Joshua	146:16-146:21	R, 403, BTS, PK, SPEC, V, O		
Paul, Joshua	146:23-146:25	R, 403, BTS, PK, SPEC, V, O		
Paul, Joshua	151:14-151:15			
Paul, Joshua	152:01-155:01	R, 403, PK, SPEC		
Paul, Joshua	155:03-155:15	R, 403, BTS, PK, SPEC, V, MIS		
Paul, Joshua	155:17-155:21	R, 403, BTS, PK, SPEC, V, MIS		
Paul, Joshua	155:24-156:13	R, 403, PK, SPEC		
Paul, Joshua	156:19-156:22			
Paul, Joshua	157:01-158:01	D 403	163 5 40	DCD 11
Paul, Joshua	158:06-160:13	R, 403	162:5-10	BSD, H
Paul, Joshua	160:22-161:17 164:12-164:13	R, 403	162:5-10 162:5-10	BSD, H BSD, H
Paul, Joshua Paul, Joshua		R, 403, BTS, PK, SPEC, V, O R, 403, BTS, PK, SPEC, V, O		· · · · · · · · · · · · · · · · · ·
Paul, Joshua Paul, Joshua	164:15-164:15 165:12-165:14	R, 403, B13, PK, SPEC, V, O	162:5-10	BSD, H
Paul, Joshua	166:02-167:01			
Paul, Joshua	167:11-167:16	R, 403, BTS, PK, SPEC, V		
Paul, Joshua	167:18-167:18	K, 403, B13, FK, 3FLC, V		
Paul, Joshua	167:20-168:12	R, 403, BTS, PK, SPEC, V		
Paul, Joshua	168:21-169:04	11, 403, 613, 1 K, 31 LC, V		
Paul, Joshua	175:25-176:03	R, 403, BTS, PK, SPEC, V, O, MIS		
Paul, Joshua	176:05-176:08	R, 403, BTS, PK, SPEC, V, O, MIS		
Paul, Joshua	176:10-176:18	R, 403, BTS, PK, SPEC, V, O		
Paul, Joshua	176:20-176:22	R, 403, BTS, PK, SPEC, V, O		
Paul, Joshua	176:24-177:08	R, 403, BTS, PK, SPEC, V, O, MIS		
Paul, Joshua	177:10-178:06	R, 403, BTS, PK, SPEC, V, O, MIS		
Paul, Joshua	180:02-180:04			
Paul, Joshua	180:10-180:16			
Paul, Joshua	180:18-181:21			
Paul, Joshua	182:02-184:14	R, 403, BTS, PK, SPEC, V, O	185:6-7; 185:9-13	Н
aul, Joshua	184:16-184:20	R, 403, BTS, PK, SPEC, V, O	185:6-7; 185:9-13	Н
Paul, Joshua	184:22-184:24	R, 403, BTS, PK, SPEC, V, O	185:6-7; 185:9-13	Н
Paul, Joshua	185:01-185:04	R, 403, BTS, PK, SPEC, V, O	185:6-7; 185:9-13	Н
Paul, Joshua	185:15-185:17	R, 403, BTS, PK, SPEC, V, O	185:6-7; 185:9-13	Н
Paul, Joshua	185:19-185:20	R, 403, BTS, PK, SPEC, V, O	185:6-7; 185:9-13	Н
Paul, Joshua	185:22-186:01	R, 403, BTS, PK, SPEC, V, O	185:6-7; 185:9-13	Н
Paul, Joshua	186:17-186:25	R, 403, BTS, PK, SPEC, V, O	185:6-7; 185:9-13	BSD, H
Paul, Joshua	189:13-189:15			
Paul, Joshua	189:24-190:18			
Paul, Joshua	191:11-192:14	R, 403, BTS, PK, SPEC, V, O		
Paul, Joshua	193:23-193:25	R, 403, BTS, PK, SPEC, V, O		
Paul, Joshua	194:02-194:03	R, 403, BTS, PK, SPEC, V, O		
Paul, Joshua	194:05-194:05	R, 403, BTS, PK, SPEC, V, O		
Paul, Joshua	194:07-194:12	R, 403, BTS, PK, SPEC, V, O		
Paul, Joshua	194:18-195:05	R, 403, BTS, PK, SPEC, V, O		

Witness	Natera Designations	Labcorp Objections	Labcorp Counter-Designations	Natera Objections	
Paul, Joshua	195:07-195:08	R, 403, BTS, PK, SPEC, V, O			
Paul, Joshua	195:10-195:13	R, 403, BTS, PK, SPEC, V, O			
Paul, Joshua	195:15-195:18	R, 403, BTS, PK, SPEC, V, O			
Paul, Joshua	195:20-195:22	R, 403, BTS, PK, SPEC, V, O			
Paul, Joshua	195:24-195:24	R, 403, BTS, PK, SPEC, V, O			
Paul, Joshua	197:10-197:11				
Paul, Joshua	197:18-197:21	R, 403, BTS, PK, SPEC, V, O, F			
Paul, Joshua	197:23-197:25	R, 403, BTS, PK, SPEC, V, O, F			
Paul, Joshua	198:02-200:02	R, 403, BTS, PK, SPEC, V, O, F			
Paul, Joshua	200:04-200:06	R, 403, BTS, PK, SPEC, V, O, F			
Paul, Joshua	200:08-200:10	R, 403, BTS, PK, SPEC, V, O, F			
Paul, Joshua	200:12-200:25	R, 403, BTS, PK, SPEC, V, O, F	K, SPEC, V, O, F 202:6-8; 202:10; 202:12; 202:14-17		
Paul, Joshua	201:02-201:03	R, 403, BTS, PK, SPEC, V, O, F	BTS, PK, SPEC, V, O, F 202:6-8; 202:10; 202:12; 202:14-17		
Paul, Joshua	201:05-201:05	R, 403, BTS, PK, SPEC, V, O, F	202:6-8; 202:10; 202:12; 202:14-17	BSD, H	
Paul, Joshua	201:07-201:09	R, 403, BTS, PK, SPEC, V, O, F	202:6-8; 202:10; 202:12; 202:14-17	BSD, H	
Paul, Joshua	201:11-201:11	R, 403, BTS, PK, SPEC, V, O, F	202:6-8; 202:10; 202:12; 202:14-17	BSD, H	
Paul, Joshua	201:13-201:14	R, 403, BTS, PK, SPEC, V, O, F	202:6-8; 202:10; 202:12; 202:14-17	BSD, H	
Paul, Joshua	201:16-201:20	R, 403, BTS, PK, SPEC, V, O, F	202:6-8; 202:10; 202:12; 202:14-17	BSD, H	
Paul, Joshua	201:22-202:01	R, 403, BTS, PK, SPEC, V, O, F, MIS	202:6-8; 202:10; 202:12; 202:14-17	BSD, H	
Paul, Joshua	202:03-202:04	R, 403, BTS, PK, SPEC, V, O, F, MIS	202:6-8; 202:10; 202:12; 202:14-17	BSD, H	
Paul, Joshua	202:19-204:11	R, 403, BTS, PK, SPEC, V, O, F, MIS	202:6-8; 202:10; 202:12; 202:14-17	BSD, H	
Paul, Joshua	204:13-203:13	R, 403, BTS, PK, SPEC, V, O, F, MIS	202:6-8; 202:10; 202:12; 202:14-17	BSD, H	
Paul, Joshua	206:12-206:14				
Paul, Joshua	206:16-206:16				
Paul, Joshua	208:13-208:20				
Paul, Joshua	209:01-210:25	R, 403, BTS, PK, SPEC, V, O	211:8-9; 211:11-13	BSD, H	
Paul, Joshua	211:02-211:07	R, 403, BTS, PK, SPEC, V, O	211:8-9; 211:11-13	BSD, H	
Paul, Joshua	212:04-212:20	R, 403, BTS, PK, SPEC, V, O	211:8-9; 211:11-13	Н	
Paul, Joshua	212:25-214:01	R, 403, BTS, PK, SPEC, V, I			
Paul, Joshua	214:08-214:21	R, 403, BTS, PK, SPEC, V			
Paul, Joshua	215:15-215:21	R, 403, BTS, PK, SPEC, V, O			
Paul, Joshua	216:12-216:22				
Paul, Joshua	217:18-217:20	R, 403, BTS, V, O, NARR			
Paul, Joshua	217:22-217:25	R, 403, BTS, V, O, NARR			
Paul, Joshua	218:02-218:03				
Paul, Joshua	218:10-218:13	R, 403, BTS, V, O, NARR			
Paul, Joshua	218:15-218:15	R, 403, BTS, V, O, NARR			
Paul, Joshua	218:17-219:16	R, 403, BTS, V, O, NARR, PK, SPEC			
Paul, Joshua	219:18-219:18	R, 403, BTS, V, O, NARR, PK, SPEC			
Paul, Joshua	219:20-220:25	R, 403, BTS, V, O, NARR, PK, SPEC			
Paul, Joshua	221:02-221:07	R, 403, BTS, V, O, NARR, PK, SPEC			
Paul, Joshua	221:18-222:05	R, 403, BTS, V, O, PK, SPEC			
Paul, Joshua	222:07-222:13	R, 403, BTS, V, O, PK, SPEC			
Paul, Joshua	222:15-222:16	R, 403, BTS, V, O, PK, SPEC			
Paul, Joshua	222:18-223:02	R, 403, BTS, V, O, PK, SPEC			
Paul, Joshua	223:04-224:11	R, 403, BTS, V, O, PK, SPEC	224:12-14; 224:16-19; 226:5-16; 226:18-227:2	BSD, H	
Paul, Joshua	225:10-225:11	R, 403, BTS, V, O, PK, SPEC	224:12-14; 224:16-19; 226:5-16; 226:18-227:2	BSD, H	
Paul, Joshua	225:13-225:15	R, 403, BTS, V, O, PK, SPEC	224:12-14; 224:16-19; 226:5-16; 226:18-227:2	BSD, H	
Paul, Joshua	227:04-227:07	R, 403, BTS, V, O, PK, SPEC	224:12-14; 224:16-19; 226:5-16; 226:18-227:2	BSD, H	
Paul, Joshua	227:09-227:18	R, 403, BTS, V, O, PK, SPEC	224:12-14; 224:16-19; 226:5-16; 226:18-227:2	BSD, H	
Paul, Joshua	227:20-228:02	R, 403, BTS, V, O, PK, SPEC	224:12-14; 224:16-19; 226:5-16; 226:18-227:2	BSD, H	
Paul, Joshua	228:04-228:05	R, 403, BTS, V, O, PK, SPEC	224:12-14; 224:16-19; 226:5-16; 226:18-227:2	BSD, H	
Paul, Joshua	228:07-228:12	R, 403, BTS, V, O, PK, SPEC, I	224:12-14; 224:16-19; 226:5-16; 226:18- 227:2; 228:13-21	BSD, H	
Paul, Joshua	229:10-229:12		,		

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 249 of 739 PageID #ួមវេទ្ធាទ

Witness	Natera Labcorp Objections		Labcorp Counter-Designations	Natera Objections
	Designations			
Paul, Joshua	229:20-230:07	R, 403, BTS, F	230:8-11	Н
Paul, Joshua	230:12-230:13	R, 403, BTS, F, V, PK, SPEC	230:8-11	Н
Paul, Joshua	230:15-231:07	R, 403, BTS, F, V, PK, SPEC	230:8-11	Н
Paul, Joshua	231:09-231:23	R, 403, BTS, F, V, PK, SPEC	230:8-11	Н

Witness	Natera	Labcorp	Labcorp Counter-Designations	Natera Objections
	Designations	Objections		
Porreca, Gregory	010:09-010:12	R, 403		
Porreca, Gregory	015:01-015:18			
Porreca, Gregory	016:05-016:11			
Porreca, Gregory	016:17-017:02			
Porreca, Gregory	017:17-017:21			
Porreca, Gregory	018:03-019:12			
Porreca, Gregory	020:18-021:22			
Porreca, Gregory	021:25-022:07			
Porreca, Gregory	022:22-023:01	AA, MIS, R, 403		
Porreca, Gregory	023:03-023:03			
Porreca, Gregory	026:23-026:24			
Porreca, Gregory	027:08-027:10			
Porreca, Gregory	027:12-027:19			
Porreca, Gregory	028:03-028:19		28:20-29:7	Н
Porreca, Gregory	029:19-029:23			
Porreca, Gregory	030:01-030:02	I		
Porreca, Gregory	030:18-030:21			
Porreca, Gregory	031:23-033:08			
Porreca, Gregory	033:15-034:09			
Porreca, Gregory	034:20-035:24	AA, R, 403		
Porreca, Gregory	036:01-036:03	AA, R, 403		
Porreca, Gregory	036:07-036:13	AA, R, 403, MIS		
Porreca, Gregory	036:16-036:20	AA, R, 403, MIS		
Porreca, Gregory	036:22-038:08	AA, I, R, 403, MIS		
Porreca, Gregory	038:11-038:18		38:19-39:4	BSD, H
Porreca, Gregory	039:05-039:07			
Porreca, Gregory	039:16-040:05			
Porreca, Gregory	040:19-041:09			
Porreca, Gregory	042:11-042:17			
Porreca, Gregory	042:21-043:21			
Porreca, Gregory	044:14-046:01			
Porreca, Gregory	046:12-046:16			
Porreca, Gregory	046:19-046:23			
Porreca, Gregory	047:01-049:03			
Porreca, Gregory	049:07-049:12			
Porreca, Gregory	049:20-050:01			
Porreca, Gregory	050:04-052:03			
Porreca, Gregory	052:19-054:16	ARG, F, R, 403	54:24-55:10	Н
Porreca, Gregory	054:18-054:19	, , , ,	54:24-55:10	H
Porreca, Gregory	055:13-057:02			
Porreca, Gregory	057:11-058:02			

Witness	Natera	Labcorp	Labcorp Counter-Designations	Natera Objections
	Designations	Objections		
Porreca, Gregory	058:10-061:14	AA, ARG, MIS,		
		R, 403		
Porreca, Gregory	065:08-067:06			
Porreca, Gregory	067:11-067:19			
Porreca, Gregory	067:21-068:10	ARG, F, NARR,		
		MIS, R, 403, I		
Porreca, Gregory	068:12-068:19	ARG, F, NARR,		
		MIS, R, 403		
Porreca, Gregory	069:10-069:18			
Porreca, Gregory	069:20-069:22			
Porreca, Gregory	069:24-070:04			
Porreca, Gregory	070:07-071:13	Withdrawn,		
		MIS, R, 403		
Porreca, Gregory	072:01-072:08			
Porreca, Gregory	072:20-073:15			
Porreca, Gregory	083:12-084:15			
Porreca, Gregory	085:20-086:10			
Porreca, Gregory	089:02-090:04	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 403
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	090:09-090:22	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 403
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	091:23-092:13	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 403
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	092:24-093:11	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 403
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
	<u> </u>		164:19; 164:21-25	
Porreca, Gregory	094:09-094:10	AA, ARG, BTS, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 403
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	

Witness	Natera	Labcorp	Labcorp Counter-Designations	Natera Objections
Dawasa Cuasawi	Designations	Objections	06:11 10: 00:22 01:6: 01:0 16:	DCD 11 402
Porreca, Gregory	094:12-094:12	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 403
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	095:19-095:25			
Porreca, Gregory	097:04-098:23			
Porreca, Gregory	099:13-100:09			
Porreca, Gregory	100:15-100:20			
Porreca, Gregory	100:15-100:20			
Porreca, Gregory	100:24-101:06			
Porreca, Gregory	102:20-103:19	AA, ARG, MIS, NARR, R, 403	86:11-18	BSD, H, 403
Porreca, Gregory	104:08-104:21			
Porreca, Gregory	105:07-106:06			
Porreca, Gregory	106:21-107:10	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 403
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	107:14-107:18	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 404
, ,		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	108:03-109:06	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 405
, , , , , ,		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	- , ,
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	110:24-111:07	ΔΔ ARG F	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 406
rorreca, Gregory	110.24 111.07	MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	636, 11, 1 00
		403	21; 133:23-134:5; 134:20-	
		1403	135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	111:09-111:14	AA ARG F	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 407
i orreca, dregory	111.05 111.14	MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	555, 11, 407
		403	21; 133:23-134:5; 134:20-	
		1703	135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porroca Gragory	112.04 112.11	AA ABC E	·	DCD 11 400
Porreca, Gregory	112:04-112:11		86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 408
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	

Witness	Natera	Labcorp	Labcorp Counter-Designations	Natera Objections
	Designations	Objections		
Porreca, Gregory	112:16-112:21	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 409
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	113:17-116:09	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 410
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	117:05-117:12	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 411
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	2027,
		403	21; 133:23-134:5; 134:20-	
		1403	135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porrosa Gragory	117:23-119:11	AA, ARG, F,	·	DCD U 412
Porreca, Gregory	117:23-119:11	1 ' ' '	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 412
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	119:22-122:04	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 413
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	122:17-123:04	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 414
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	123:10-124:23	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 415
, ,		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	, ,
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	125:16-125:19	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 416
. orreca, Gregory	123.10 123.13	MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	555, 11, 410
		403	21; 133:23-134:5; 134:20-	
		1403	135:4; 159:9-160:3; 163:22-	
Darross Cra	125,24 120,24	AA ABC 5	164:19; 164:21-25	DCD 11 447
Porreca, Gregory	125:21-129:21	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 417
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	

Witness	Natera	Labcorp	Labcorp Counter-Designations	Natera Objections
<u> </u>	Designations	Objections	05.44.40.00.22.04.5.04.0.45	DCD 11 440
Porreca, Gregory	130:06-130:19	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 418
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	131:23-132:05	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 419
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	132:07-132:11	AA ARG F	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 420
i orreca, Gregory	132.07 132.11	MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	000,11, 120
		403	21; 133:23-134:5; 134:20-	
		403		
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	133:01-133:13	1 ' ' '	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 421
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	135:16-137:18	AA, ARG, F,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 422
		MIS, NARR, R,	92:14-21; 93:23-94:1; 133:15-	
		403	21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	139:06-141:15	MIS, NARR, R,	101.13, 101.21 23	
rorreca, dregory	133.00-141.13	403		
Dawroon Cuanani	141.20 142.02		145.17 20. 145.22 146.2	DCD II
Porreca, Gregory	141:20-142:02	MIS, NARR, R,	145:17-20; 145:22-146:2	BSD, H
	110.05.110.10	403		
Porreca, Gregory	142:05-143:12	MIS, NARR, R,	145:17-20; 145:22-146:2	BSD, H
		403		
Porreca, Gregory	143:14-143:16	MIS, NARR, R,	145:17-20; 145:22-146:2	BSD, H
		403		
Porreca, Gregory	144:01-144:03	MIS, NARR, R,	145:17-20; 145:22-146:2	BSD, H
		403		
Porreca, Gregory	144:05-144:08	MIS, NARR, R,	145:17-20; 145:22-146:2	BSD, H
		403		
Porreca, Gregory	144:12-145:14	MIS, NARR, R,	145:17-20; 145:22-146:2	BSD, H
, - 20-1		403	,	- ,
Porreca, Gregory	146:12-146:19	MIS, NARR, R,	145:17-20; 145:22-146:2	BSD, H
. Streed, Gregory	110.12 170.13	403	1.3.17 20, 173.22 170.2	555, 11
Dorrosa Cragari	147.10 150.05		+	
Porreca, Gregory	147:10-150:05	MIS, NARR, R,		
	147 04 117 11	403	<u> </u>	
Porreca, Gregory	147:21-148:01	MIS, NARR, R,		
		403		

Witness	Natera Designations	Labcorp Objections	Labcorp Counter-Designations	Natera Objections
Porreca, Gregory	148:03-148:03	MIS, NARR, R,	+	
r orreca, Gregory	140.03 140.03	403		
Porreca, Gregory	148:06-148:13	MIS, NARR, R,	151:12-21; 152:23-153:5	BSD, H
r orreca, cregory	110.00 110.13	403	131.12 21, 132.23 133.3	555,11
Porreca, Gregory	148:15-149:07	MIS, NARR, R,	151:12-21; 152:23-153:5	BSD, H
. 0.1.200, 0.2801,	110113 113107	403	131.12 21, 132.23 133.3	202)
Porreca, Gregory	150:19-151:01	MIS, NARR, R,	151:12-21; 152:23-153:5	BSD, H
		403		202,
Porreca, Gregory	153:12-153:18			
Porreca, Gregory	154:06-154:09			
Porreca, Gregory	154:15-156:03			
Porreca, Gregory	156:05-156:24			
Porreca, Gregory	157:01-157:10			
Porreca, Gregory	157:13-157:25			
Porreca, Gregory	159:05-159:08			
Porreca, Gregory	160:19-160:20			
Porreca, Gregory	161:03-161:18			
Porreca, Gregory	161:25-162:04			
Porreca, Gregory	162:20-163:10			
Porreca, Gregory	163:16-163:21			
Porreca, Gregory	166:18-167:06	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 403
		, , , , , , , , , , , , , , , , , , , ,	92:14-21; 93:23-94:1; 133:15-	,,
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	168:03-168:13	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 404
, , ,			92:14-21; 93:23-94:1; 133:15-	, ,
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	168:20-169:24	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 405
			92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	170:02-170:04	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 406
			92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
		<u> </u>	164:19; 164:21-25	
Porreca, Gregory	171:01-171:17	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 407
-			92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	

Witness	Natera	Labcorp	Labcorp Counter-Designations	Natera Objections
Dawasa Cuasawi	Designations	Objections	00.11 10. 00.22 01.0. 01.0 10.	DCD 11 400
Porreca, Gregory	171:23-172:03	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 408
			92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	172:05-172:11	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 409
			92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	173:18-174:08	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 410
			92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	174:11-174:21	MIS. R. 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 411
, , , , ,			92:14-21; 93:23-94:1; 133:15-	- , ,
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	174:23-175:04	MIS D 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 412
roneca, diegory	1/4.23-1/3.04	Wii3, IX, 403	92:14-21; 93:23-94:1; 133:15-	650, 11, 412
			21; 133:23-134:5; 134:20-	
			· ·	
			135:4; 159:9-160:3; 163:22-	
D	475 07 475 40	NAIC D 403	164:19; 164:21-25	DCD 11 442
Porreca, Gregory	175:07-175:10	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 413
			92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	175:23-176:11	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 414
			92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	176:13-176:24	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 415
			92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	177:07-177:16	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 416
,			92:14-21; 93:23-94:1; 133:15-	, ,
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
	1		164:19; 164:21-25	

Witness	Natera	Labcorp	Labcorp Counter-Designations	Natera Objections
	Designations	Objections		
Porreca, Gregory	177:25-178:25	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 417
			92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	179:16-180:03	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 418
			92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	186:13-187:16	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 419
			92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	187:22-188:16	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 420
			92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	188:22-190:05	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 421
			92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	190:19-191:01			
Porreca, Gregory	191:15-192:06			
Porreca, Gregory	193:01-193:18			
Porreca, Gregory	196:05-196:07			
Porreca, Gregory	196:11-197:24			
Porreca, Gregory	198:09-198:10	AA, MIS, R, 403,		
		V		
Porreca, Gregory	198:12-198:12	R, 403, V		
Porreca, Gregory	198:22-199:10			
Porreca, Gregory	199:15-199:16			
Porreca, Gregory	199:21-201:01			
Porreca, Gregory	201:06-202:14			
Porreca, Gregory	203:04-205:09			
Porreca, Gregory	206:01-206:02			
Porreca, Gregory	206:05-206:16			
Porreca, Gregory	206:19-208:13			
Porreca, Gregory	209:09-213:18			
Porreca, Gregory	218:03-218:09	AA, ARG, MIS,		
		R, 403		

Witness	Natera	Labcorp	Labcorp Counter-Designations	Natera Objections
	Designations	Objections		
Porreca, Gregory	218:11-218:12	AA, ARG, MIS,		
		R, 403		
Porreca, Gregory	219:06-219:11	AA, ARG, MIS,		
		R, 403		
Porreca, Gregory	219:24-220:04	AA, ARG, MIS,		
		R, 403		
Porreca, Gregory	220:06-220:12			
Porreca, Gregory	220:15-220:21			
Porreca, Gregory	221:25-222:05			
Porreca, Gregory	223:16-223:24			
Porreca, Gregory	224:03-224:13			
Porreca, Gregory	224:18-226:03			
Porreca, Gregory	226:20-228:16			
Porreca, Gregory	229:08-230:01			
Porreca, Gregory	236:10-237:02			
Porreca, Gregory	238:14-241:05			
Porreca, Gregory	241:08-242:01			
Porreca, Gregory	243:03-243:14			
Porreca, Gregory	243:21-245:06	F, OB, R, 403		
Porreca, Gregory	250:06-250:24	MIS, R, 403		
Porreca, Gregory	251:01-251:02			
Porreca, Gregory	254:04-255:13			
Porreca, Gregory	255:18-256:13			
Porreca, Gregory	263:02-263:18			
Porreca, Gregory	263:24-264:14			
Porreca, Gregory	265:06-265:11	ARG, MIS,	259:23-260:6; 265:16-20	Н
,		NARR, R, 403		
Porreca, Gregory	265:13-265:15	ARG, MIS,	259:23-260:6; 265:16-20	Н
, ,		NARR, R, 403	· ·	
Porreca, Gregory	265:21-266:13			
Porreca, Gregory	267:03-267:04			
Porreca, Gregory	267:11-267:24			
Porreca, Gregory	268:16-270:06			
Porreca, Gregory	271:01-271:02			
Porreca, Gregory	271:06-272:16			
Porreca, Gregory	272:21-274:20			
Porreca, Gregory	275:10-275:16			
Porreca, Gregory	275:19-275:22			
Porreca, Gregory	276:02-276:04			
Porreca, Gregory	276:07-276:08			
Porreca, Gregory	276:12-276:18			
Porreca, Gregory	276:23-278:01			
Porreca, Gregory	278:09-280:22			
Porreca, Gregory	280:24-280:25			
Porreca, Gregory	281:07-281:20	MIS, R, 403	282:2-14	BSD, H

Witness	Natera	Labcorp	Labcorp Counter-Designations	Natera Objections
	Designations	Objections		•
Porreca, Gregory	282:20-282:22	MIS, R, 403	282:2-14	BSD, H
Porreca, Gregory	283:06-284:02	MIS, R, 403, O,	259:23-260:6; 265:16-20; 282:2-	BSD, H
		LC	14; 288:3-9	
Porreca, Gregory	284:04-285:19	MIS, R, 403, O,	259:23-260:6; 265:16-20; 282:2-	BSD, H
		LC	14; 288:3-9	
Porreca, Gregory	286:04-288:02	MIS, R, 403, O,	259:23-260:6; 265:16-20; 282:2-	BSD, H
		LC	14; 288:3-9	
Porreca, Gregory	288:10-290:14	MIS, R, 403, O,	259:23-260:6; 265:16-20; 282:2-	BSD, H
		LC	14; 288:3-9	
Porreca, Gregory	290:19-291:05	MIS, OB, R, 403,	259:23-260:6; 265:16-20; 282:2-	BSD, H
		O, LC	14; 288:3-9	
Porreca, Gregory	291:07-291:13	MIS, R, 403, O,	259:23-260:6; 265:16-20; 282:2-	BSD, H
		LC	14; 288:3-9	
Porreca, Gregory	291:18-292:08	MIS, R, 403, O,	259:23-260:6; 265:16-20; 282:2-	BSD, H
		LC	14; 288:3-9	
Porreca, Gregory	292:10-292:24	MIS, OB, R, 403,	259:23-260:6; 265:16-20; 282:2-	BSD, H
		O, LC	14; 288:3-9	
Porreca, Gregory	293:13-293:15	MIS, R, 403, O,		
		LC		
Porreca, Gregory	293:23-286:08	MIS, R, 403, O,		
		LC		
Porreca, Gregory	297:01-298:04	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 403
			92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	298:10-299:19	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 404
			92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	300:14-301:08	MIS, R, 403	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 405
			92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	301:15-304:11	Withdrawn,	86:11-18; 90:23-91:6; 91:8-16;	BSD, H, 406
		MIS, R, 403	92:14-21; 93:23-94:1; 133:15-	
			21; 133:23-134:5; 134:20-	
			135:4; 159:9-160:3; 163:22-	
			164:19; 164:21-25	
Porreca, Gregory	304:14-304:19			
Porreca, Gregory	304:22-304:22			

Witness	Natera	Labcorp	Labcorp Counter-Designations	Natera Objections
	Designations	Objections		
Porreca, Gregory	305:04-307:25	AA, ARG, MIS,	308:1-6; 308:8-13; 311:4-5;	BSD, H
		NARR, PK, R,	311:7-8; 314:8-11	
		SPEC, 403, V		
Porreca, Gregory	310:14-310:19	AA, ARG, MIS,	308:1-6; 308:8-13; 311:4-5;	BSD, H
		NARR, PK, R,	311:7-8; 314:8-11	
		SPEC, 403, V		
Porreca, Gregory	310:21-310:24	AA, ARG, MIS,	308:1-6; 308:8-13; 311:4-5;	BSD, H
		NARR, PK, R,	311:7-8; 314:8-11	
		SPEC, 403, V		
Porreca, Gregory	311:01-311:03	AA, ARG, MIS,	308:1-6; 308:8-13; 311:4-5;	BSD, H
		NARR, PK, R,	311:7-8; 314:8-11	
		SPEC, 403, V		
Porreca, Gregory	311:09-311:14	AA, ARG, MIS,	308:1-6; 308:8-13; 311:4-5;	BSD, H
		NARR, PK, R,	311:7-8; 314:8-11	
		SPEC, 403, V		
Porreca, Gregory	311:16-312:09	AA, ARG, MIS,	308:1-6; 308:8-13; 311:4-5;	BSD, H
, ,		NARR, PK, R,	311:7-8; 314:8-11	,
		SPEC, 403, V	,	
Porreca, Gregory	312:11-313:01	AA, ARG, MIS,	308:1-6; 308:8-13; 311:4-5;	BSD, H
, , ,		NARR, PK, R,	311:7-8; 314:8-11	•
		SPEC, 403, V		
Porreca, Gregory	313:03-313:13	AA, ARG, MIS,	308:1-6; 308:8-13; 311:4-5;	BSD, H
, , , , , ,		NARR, PK, R,	311:7-8; 314:8-11	- ,
		SPEC, 403, V		
Porreca, Gregory	313:15-313:22	AA, ARG, MIS,	308:1-6; 308:8-13; 311:4-5;	BSD, H
		NARR, PK, R,	311:7-8; 314:8-11	,
		SPEC, 403, V	, , , , , , , , , , , , , , , , , , , ,	
Porreca, Gregory	314:03-314:05	AA, ARG, MIS,	308:1-6; 308:8-13; 311:4-5;	BSD, H
romeda, eregory	32 1103 32 1103	NARR, PK, R,	311:7-8; 314:8-11	202,
		SPEC, 403, V	011.7 0, 01 01	
Porreca, Gregory	314:07-314:07	AA, ARG, MIS,	308:1-6; 308:8-13; 311:4-5;	BSD, H
Torreca, Gregory	311.07 311.07	NARR, PK, R,	311:7-8; 314:8-11	555,11
		SPEC, 403, V	311.7 0, 311.0 11	
Porreca, Gregory	316:04-316:13	AA, ARG, MIS,	308:1-6; 308:8-13; 311:4-5;	BSD, H
Torreca, Gregory	310.04 310.13	NARR, PK, R,	311:7-8; 314:8-11	030,11
		SPEC, 403, V	311.7 0, 314.0 11	
Porreca, Gregory	316:15-316:16	51 LC, 703, V		
Porreca, Gregory	317:05-317:09			
Porreca, Gregory	317:12-320:09	AA, ARG, MIS,		
Torreca, diegory	317.12-320.09	NARR, PK, R,		
		SPEC, 403, V		
Porroca Gragori	220:16 221:02		+	
Porreca, Gregory	320:16-321:02	AA, ARG, MIS,		
		NARR, PK, R,		
		SPEC, 403, V		

Witness	Natera	Labcorp	Labcorp Counter-Designations	Natera Objections
	Designations	Objections		
Porreca, Gregory	321:04-322:03	AA, ARG, MIS,		
		NARR, PK, R,		
		SPEC, 403, V		
Porreca, Gregory	322:05-322:05	AA, ARG, MIS,		
		NARR, PK, R,		
		SPEC, 403, V		

Witness	Natera	Labcorp Objections	Labcorp Counter-Designations	Natera Objections
Charact Han	Designations			
Stuart, Jim Stuart, Jim	005:21-006:02 006:15-010:20	P 402		
Stuart, Jim		R, 403, BTS, PK, SPEC, V, O		
Stuart, Jim		R, 403, BTS, PK, SPEC, V, O		
Stuart, Jim		R, 403, BTS, PK, SPEC, V, O		
Stuart, Jim	015:04-017:11	R, 403, BTS, PK, SPEC, V, O		
Stuart, Jim	018:06-018:24			
Stuart, Jim	019:01-019:23			
Stuart, Jim		R, 403, BTS, V, PK, SPEC		
Stuart, Jim Stuart, Jim		R, 403, BTS, V, PK, SPEC R, 403, BTS, V, PK, SPEC		
Stuart, Jim		R, 403, BTS, V, PK, SPEC		
Stuart, Jim		R, 403, BTS, V, PK, SPEC, CP		
Stuart, Jim		R, 403, BTS, V, PK, SPEC, CP		
Stuart, Jim		R, 403, BTS, V, PK, SPEC, CP		
Stuart, Jim		R, 403, BTS, V, PK, SPEC		
Stuart, Jim		R, 403, BTS, V, PK, SPEC		
Stuart, Jim		R, 403, BTS, V, PK, SPEC, CP		
Stuart, Jim Stuart, Jim		R, 403, BTS, V, PK, SPEC R, 403, BTS, V, PK, SPEC		
Stuart, Jim		R, 403, BTS, V, PK, SPEC		
Stuart, Jim		R, 403, BTS, V, PK, SPEC		
Stuart, Jim		R, 403, BTS, V, PK, SPEC		
Stuart, Jim		R, 403, BTS, V, PK, SPEC		
Stuart, Jim		R, 403, BTS, V, PK, SPEC		
Stuart, Jim		R, 403, BTS, V, PK, SPEC		
Stuart, Jim Stuart, Jim		R, 403, BTS, V, PK, SPEC R, 403, BTS, V, PK, SPEC		
Stuart, Jim Stuart, Jim		R, 403, BTS, V, PK, SPEC, F		
Stuart, Jim		R, 403, BTS, V, F		
Stuart, Jim		R, 403, BTS, V, F	56:21; 57:08-16	OB, H
Stuart, Jim		R, 403, BTS, V, F	58:16-19; 58:21-24; 59:1-2; 59:4-8	BSD, H
Stuart, Jim		R, 403, BTS, V, F	58:16-19; 58:21-24; 59:1-2; 59:4-8	BSD, H
Stuart, Jim		R, 403, BTS, V, F	58:16-19; 58:21-24; 59:1-2; 59:4-8	BSD, H
Stuart, Jim		R, 403, BTS, V, F, PK, SPEC	65:06-07; 65:09-11; 67:11-68:02	BSD, H BSD, H
Stuart, Jim Stuart, Jim		R, 403, BTS, V, F, PK, SPEC R, 403, BTS, V, F, PK, SPEC	65:06-07; 65:09-11; 67:11-68:02 65:06-07; 65:09-11; 67:11-68:02	BSD, H
Stuart, Jim		R, 403, BTS, V, F, PK, SPEC	65:06-07; 65:09-11; 67:11-68:02	BSD, H
Stuart, Jim		R, 403, BTS, V, F, PK, SPEC	65:06-07; 65:09-11; 67:11-68:02	BSD, H
Stuart, Jim		R, 403, BTS, V, F, PK, SPEC	65:06-07; 65:09-11; 67:11-68:02	BSD, H
Stuart, Jim	065:25-066:20	R, 403, BTS, V, PK, SPEC	65:06-07; 65:09-11; 67:11-68:02	BSD, H
Stuart, Jim		R, 403, BTS, V, PK, SPEC	65:06-07; 65:09-11; 67:11-68:02	BSD, H
Stuart, Jim		R, 403, BTS, V, PK, SPEC	65:06-07; 65:09-11; 67:11-68:02	BSD, H
Stuart, Jim Stuart, Jim		R, 403, BTS, V, PK, SPEC R, 403, BTS, V, PK, SPEC	65:06-07; 65:09-11; 67:11-68:02 65:06-07; 65:09-11; 67:11-68:02	BSD, H BSD, H
Stuart, Jim		R, 403, BTS, V, PK, SPEC, F	65:06-07; 65:09-11; 67:11-68:02	BSD, H
Stuart, Jim		R, 403, BTS, V, PK, SPEC, F	65:06-07; 65:09-11; 67:11-68:02	BSD, H
Stuart, Jim		R, 403, BTS, V, PK, SPEC, F	65:06-07; 65:09-11; 67:11-68:02	BSD, H
Stuart, Jim		R, 403, BTS, V, PK, SPEC	65:06-07; 65:09-11; 67:11-68:02	BSD, H
Stuart, Jim		R, 403, BTS, V, PK, SPEC	65:06-07; 65:09-11; 67:11-68:02	BSD, H
Stuart, Jim		R, 403, BTS, V, PK, SPEC, O	80:2-14; 84:16-86:24; 89:08-11; 90:18-91:08	BSD, H
Stuart, Jim Stuart, Jim		R, 403, BTS, V, PK, SPEC R, 403, BTS, V, PK, SPEC, I	80:2-14; 84:16-86:24; 89:08-11; 90:18-91:08 80:2-14; 84:16-86:24; 89:08-11; 90:18-91:08	BSD, H BSD, H
Stuart, Jim		R, 403, BTS, V, PK, SPEC, I	99:14-23	BSD, H
Stuart, Jim		R, 403, BTS, V, PK, SPEC	99:14-23	BSD, H
Stuart, Jim		R, 403, BTS, V, PK, SPEC	99:14-23	BSD, H
Stuart, Jim	100:08-100:14	R, 403, BTS, V, PK, SPEC		·
Stuart, Jim		R, 403, BTS, V, PK, SPEC		-
Stuart, Jim		R, 403, BTS, V, PK, SPEC, F	103:02-05; 104:16-19; 104:21-105:07; 105:09-13	BSD, H
Stuart, Jim		R, 403, BTS, V, PK, SPEC, F	103:02-05; 104:16-19; 104:21-105:07; 105:09-13	BSD, H
Stuart, Jim Stuart, Jim		R, 403, BTS, V, PK, SPEC, F R, 403, BTS, V, PK, SPEC, F, I	103:02-05; 104:16-19; 104:21-105:07; 105:09-13 103:02-05; 104:16-19; 104:21-105:07; 105:09-13; 67:11-68:02	BSD, H BSD, H
Stuart, Jim Stuart, Jim		R, 403, BTS, V, PK, SPEC, F, I	103:02-05; 104:16-19; 104:21-105:07; 105:09-13; 67:11-68:02	BSD, H
Stuart, Jim		R, 403, BTS, V, PK, SPEC, F	103:02-05; 104:16-19; 104:21-105:07; 105:09-13; 67:11-68:02	BSD, H
Stuart, Jim		R, 403, BTS, V, PK, SPEC, F	103:02-05; 104:16-19; 104:21-105:07; 105:09-13; 67:11-68:02	BSD, H
Stuart, Jim	109:07-111:01	R, 403, BTS, V, PK, SPEC, F	103:02-05; 104:16-19; 104:21-105:07; 105:09-13; 67:11-68:02; 111:02-03; 111:14-25; 112:11-19; 112: 21-23	BSD, H
Stuart, Jim		R, 403, BTS, V, PK, SPEC, F	103:02-05; 104:16-19; 104:21-105:07; 105:09-13; 67:11-68:02; 111:02-03; 111:14-25; 112:11-19; 112: 21-23	BSD, H
Stuart, Jim		Not Designated		
Stuart, Jim		R, 403, BTS, V, PK, SPEC		
Stuart, Jim Stuart, Jim		R, 403, BTS, V, PK, SPEC R, 403, BTS, V, PK, SPEC		
Stuart, Jim	120:04-122:04			
Stuart, Jim	124:18-126:17			
Stuart, Jim		R, 403, BTS, V, PK, SPEC, O		
Stuart, Jim	131:24-132:19	R, 403, BTS, V, PK, SPEC		
Stuart, Jim		R, 403, BTS, V, PK, SPEC		
Stuart, Jim		R, 403, BTS, V, PK, SPEC		
Stuart, Jim		R, 403, BTS, V, PK, SPEC, LC	137:25-138:03; 141:13-17; 141:19	BSD, H
Stuart, Jim Stuart, Jim		R, 403, BTS, V, PK, SPEC, LC	137:25-138:03; 141:13-17; 141:19 137:25-138:03; 141:13-17; 141:19	BSD, H BSD, H
Stuart, Jim Stuart, Jim		R, 403, BTS, V, PK, SPEC, LC R, 403, BTS, V, PK, SPEC, LC	137:25-138:03; 141:13-17; 141:19	BSD, H
Stuart, Jim		R, 403, BTS, V, PK, SPEC, LC	137:25-138:03; 141:13-17; 141:19	BSD, H
Stuart, Jim		R, 403, BTS, V, PK, SPEC, LC	137:25-138:03; 141:13-17; 141:19	BSD, H
			137:25-138:03; 141:13-17; 141:19	BSD, H
Stuart, Jim Stuart, Jim		R, 403, BTS, V, PK, SPEC, LC R, 403, BTS, V, PK, SPEC, LC	137:25-138:03; 141:13-17; 141:19	BSD, H

Witness	Natera	Labcorp Objections	Labcorp Counter-Designations	Natera Objections
	Designations			
Stuart, Jim	142:22-143:09	R, 403, BTS, V, PK, SPEC, LC	137:25-138:03; 141:13-17; 141:19	BSD, H
Stuart, Jim	143:22-144:21	R, 403, BTS, V, PK, SPEC		
Stuart, Jim	144:23-146:09	R, 403, V, SPEC, BTS, PK, LC, O	67:11-68:02; 103:2-5	BSD, H
Stuart, Jim	146:11-147:21	R, 403, V, SPEC, BTS, PK, LC, O	67:11-68:02; 103:2-5	BSD, H
Stuart, Jim	147:23-151:06	R, 403, V, SPEC, BTS, PK	67:11-68:02; 103:2-5	BSD, H
Stuart, Jim	151:17-152:05	R, 403, V, I	67:11-68:02; 103:2-5	BSD, H
Stuart lim	152:07-152:14	B 403 V	67:11-68:02: 103:2-5	BCD H

Witness	Natera Designations	Labcorp Objections	LabcorpCounter-Designations	Natera Objections
Salari, Raheleh	008:04-008:20	,		
Salari, Raheleh	015:15-015:17			
Salari, Raheleh	015:22-015:23			
Salari, Raheleh	016:13-016:17			
Salari, Raheleh	017:09-018:14			
Salari, Raheleh	019:13-020:16			
Salari, Raheleh	020:19-020:19			
Salari, Raheleh	023:24-024:12			
Salari, Raheleh	024:21-026:07			
Salari, Raheleh	027:05-027:10			
		Н		
Salari, Raheleh				
Salari, Raheleh		Н		
Salari, Raheleh		H, O		
Salari, Raheleh		Н, О		
Salari, Raheleh	_	Н, О	20.05.40.0.40.40.	
Salari, Raheleh	036:18-037:23		39:25-40:3; 42:14-43:4	F, SPEC
Salari, Raheleh	038:09-038:16		39:25-40:3; 42:14-43:4	F, SPEC
Salari, Raheleh		Н	39:25-40:3; 42:14-43:4	F, SPEC
Salari, Raheleh		Н, О	56:7-12	I
Salari, Raheleh		Н		
Salari, Raheleh	056:13-056:15	Н		
Salari, Raheleh	057:06-057:20	Н		
Salari, Raheleh	058:06-058:08	Н		
Salari, Raheleh	068:09-068:11	Н	69:2-4	BSD
Salari, Raheleh	068:13-068:17	Н	69:2-4	BSD
Salari, Raheleh	069:23-070:14	Н		
Salari, Raheleh	071:05-071:09	Н	71:10-12	
Salari, Raheleh	071:22-072:05	Н	71:10-12	
Salari, Raheleh	072:21-073:09	Н		
Salari, Raheleh	074:06-074:18	ОВ, Н		
Salari, Raheleh		H		
Salari, Raheleh		Н		
Salari, Raheleh		Н		
Salari, Raheleh	076:23-077:04		77:5-10; 77:19-22, 78:8-13	
Salari, Raheleh	079:22-080:25		7713 10,77113 22,7010 13	
Salari, Raheleh		H, OB		
Salari, Raheleh		н, ов Н		
Salari, Raheleh		H	83:23-84:2	
Salari, Raheleh		Н	05.25 04.2	
Salari, Raheleh		п Н		
Salari, Raheleh		п Н		
· · · · · · · · · · · · · · · · · · ·			02:1 0	BSD
Salari, Raheleh	091:22-091:24		93:1-9	
Salari, Raheleh		Н	93:1-9	BSD
Salari, Raheleh		Н	93:1-9	BSD
Salari, Raheleh	094:09-094:12			
Salari, Raheleh	094:15-095:14			
Salari, Raheleh		H		
Salari, Raheleh		Н		
Salari, Raheleh		Н	98:12-16	
Salari, Raheleh		Н	98:12-16	
Salari, Raheleh	101:10-101:16	Н	109:10-17	CP, I
Salari, Raheleh	101:19-101:19	Н	109:10-17	
Salari, Raheleh	103:04-103:09	Н		
Salari, Raheleh	103:12-103:13	Н		

Witness	Natera	Labcorp	LabcorpCounter-Designations	Natera
	Designations	Objections		Objections
Salari, Raheleh	103:16-103:16	Н		
Salari, Raheleh	103:19-104:02	Н	104:23-25	
Salari, Raheleh	104:06-104:12	Н	104:23-25	
Salari, Raheleh	104:17-107:20	Н	104:23-25	
Salari, Raheleh	106:04-106:23	Н	64:6-13, 115:20-117:5, 117:10-11, 118:6-23	BSD, F, I, SPEC
Salari, Raheleh	107:14-107:25	Н	108:1-15	
Salari, Raheleh	109:18-110:12	Н		
Salari, Raheleh	110:22-110:25	Н		
Salari, Raheleh	111:09-111:11	Н, О	109:10-17	CP, I, MIS
Salari, Raheleh	111:16-112:08	Н, О	109:10-17	CP, I, MIS
Salari, Raheleh	112:11-112:11	Н, О	109:10-17	CP, I, MIS
Salari, Raheleh	112:20-113:08	Н, О	109:10-17	CP, I, MIS
Salari, Raheleh	113:13-113:19	Н	109:10-17	CP, I, MIS
Salari, Raheleh	114:11-114:18	Н		
Salari, Raheleh	115:08-115:19	Н		
Salari, Raheleh	122:10-122:23	Н		
Salari, Raheleh	124:10-124:20	Н		
Salari, Raheleh	125:10-125:14	Н		
Salari, Raheleh	125:18-125:24	Н		
Salari, Raheleh	127:03-127:05	Н		
Salari, Raheleh	127:07-127:11	Н		
Salari, Raheleh	127:15-127:16	Н		
Salari, Raheleh	130:11-132:02	Н	64:6-13, 115:20-117:5, 117:10-11, 118:6-23, 132:8-9, 132:13	BSD, F, I, SPEC

Witness	Natera	Labcorp Objections	Labcorp Counter-Designations	Natera Objections
	Designations		, -	-
Swamy, Sajani	008:09-008:17			
Swamy, Sajani	012:03-015:02	R, 403, V		
Swamy, Sajani	015:05-015:09	V		
Swamy, Sajani	015:05-015:09	V		
Swamy, Sajani	015:25-016:25	R, 403, V, SPEC		
Swamy, Sajani	018:21-020:02	R, 403, V	21:19-22:8; 22:12-23:5	BSD, H
Swamy, Sajani	020:18-021:08	R, 403, V, F	21:19-22:8; 22:12-23:5	BSD, H
Swamy, Sajani	021:10-021:18	R, 403, V, F	21:19-22:8; 22:12-23:5	BSD, H
Swamy, Sajani			24:9-24:23	BSD, H
Swamy, Sajani		R, 403, V, F, MIS	24:9-24:23	BSD, H
Swamy, Sajani	031:12-032:01	,, , , -		1
Swamy, Sajani	032:08-032:11			
Swamy, Sajani	032:13-032:13			
Swamy, Sajani	032:15-032:16			+
Swamy, Sajani	032:19-032:19			
Swamy, Sajani	032:21-033:03			
Swamy, Sajani	032:21-033:03	B 403 V E		
				+
Swamy, Sajani	033:18-033:21		27.40.45.44.00	
Swamy, Sajani		R, 403, V, F, MIS	37:10-15; 41:6-8	H
Swamy, Sajani			37:10-15; 41:6-8	H
Swamy, Sajani		R, 403, V, SPEC, PK, F	37:10-15	Н
Swamy, Sajani		R, 403, V, SPEC, PK, F	37:10-15	Н
Swamy, Sajani		R, 403, V, SPEC, PK, F	37:10-15; 41:6-8	Н
Swamy, Sajani			37:10-15; 41:6-8	Н
Swamy, Sajani		R, 403, SPEC, PK, F, O	37:10-15; 41:6-8	Н
Swamy, Sajani		R, 403, SPEC, PK, F, O	37:10-15; 41:6-8	Н
Swamy, Sajani		R, 403, SPEC, PK, F	37:10-15; 41:6-8	Н
Swamy, Sajani		R, 403, V, SPEC, PK, F, LC, O	37:10-15; 41:6-8	Н
Swamy, Sajani		R, 403, V, SPEC, PK, F, LC, O	37:10-15; 41:6-8	Н
Swamy, Sajani	044:07-044:08	R, 403, V, SPEC, PK, F, LC, O	37:10-15; 41:6-8	Н
Swamy, Sajani		R, 403, V, SPEC, PK, F, LC, O	37:10-15; 41:6-8	Н
Swamy, Sajani		R, 403, V, SPEC, PK, F, LC, O	37:10-15; 41:6-8	Н
Swamy, Sajani	044:20-044:21	R, 403, V, SPEC, PK, F, LC, O	37:10-15; 41:6-8	Н
Swamy, Sajani			37:10-15; 41:6-8	Н
Swamy, Sajani		R, 403, V, SPEC, PK, F, LC, O	37:10-15; 41:6-8	Н
Swamy, Sajani		R, 403, V, SPEC, PK, F, LC, O	37:10-15; 41:6-8; 46:19-47:4	BSD, H
Swamy, Sajani		R, 403, V, SPEC, PK, F, LC, O	37:10-15; 41:6-8; 46:19-47:4	BSD, H
Swamy, Sajani		R, 403, V, SPEC, PK, F, LC	37:10-15; 41:6-8; 46:19-47:4	BSD, H
Swamy, Sajani		R, 403, V, SPEC, PK, F, LC	37:10-15; 41:6-8; 46:19-47:4	BSD, H
Swamy, Sajani			37:10-15; 41:6-8; 46:19-47:4	BSD, H
Swamy, Sajani		R, 403, V, SPEC, PK, F, LC	37:10-15; 41:6-8; 46:19-47:4	BSD, H
Swamy, Sajani		R, 403, V SPEC, PK, F, LC, AA	37:10-15; 41:6-8; 46:19-47:4	BSD, H
Swamy, Sajani		R, 403, V SPEC, PK, F, LC	37:10-15; 41:6-8; 46:19-47:4	BSD, H
Swamy, Sajani	050:17-050:18			
Swamy, Sajani				
Swamy, Sajani		R, 403, V, PK, F, LC		
Swamy, Sajani		R, 403, V, PK, F, LC		
Swamy, Sajani		R, 403, V, PK, F, LC		
Swamy, Sajani				
Swamy, Sajani	053:14-053:22	R, 403, V, F, LC		
Swamy, Sajani	054:16-055:01			
Swamy, Sajani	060:07-060:14	R, 403, V, AA		
Swamy, Sajani	060:16-060:16	R, 403, V		
Swamy, Sajani	060:18-060:22	R, 403, V, F, O, SPEC, PK		
Swamy, Sajani	060:25-061:05	R, 403, V, F, O, SPEC, PK	64:8-11; 64:13-65:4; 65:21-66:15	Н
Swamy, Sajani	061:07-061:08	R, 403, V, F, O, SPEC, PK	64:8-11; 64:13-65:4; 65:21-66:15	Н
Swamy, Sajani		R, 403, V, F, O, SPEC, PK	64:8-11; 64:13-65:4; 65:21-66:15	Н
Swamy, Sajani		R, 403, V, F, O, SPEC, PK	64:8-11; 64:13-65:4; 65:21-66:15	Н
Swamy, Sajani		R, 403, V, F, O, SPEC, PK	64:8-11; 64:13-65:4; 65:21-66:15	H
Swamy, Sajani		R, 403, V, F, O, SPEC, PK	64:8-11; 64:13-65:4; 65:21-66:15	H
Swamy, Sajani	065:11-065:19		64:8-11; 64:13-65:4; 65:21-66:15	Н
Swamy, Sajani		R, 403, V, F, O, SPEC, PK, CP	64:8-11; 64:13-65:4; 65:21-66:15	H
Swamy, Sajani		R, 403, V, F, O, SPEC, PK, CP	64:8-11; 64:13-65:4; 65:21-66:15	Н
Swamy, Sajani		R, 403, V, F, O, SPEC, PK, IH	64:8-11; 64:13-65:4; 65:21-66:15	H
Swamy, Sajani		R, 403, V, F, O, SPEC, PK, IH	64:8-11; 64:13-65:4; 65:21-66:15	BSD, H
Swamy, Sajani		R, 403, V, F, O, SPEC, PK, IH	64:8-11; 64:13-65:4; 65:21-66:15; 71:11-18; 72:21-74:1	взр, п Н
		R, 403, V, F, O, SPEC, PK, IH R, 403, V, F, O, SPEC, PK, IH, NARR, MIS	64:8-11; 64:13-65:4; 65:21-66:15; 71:11-18; 72:21-74:1	
Swamy, Sajani				Н
Swamy, Sajani		R, 403, V, F, O, SPEC, PK, IH, NARR, MIS	64:8-11; 64:13-65:4; 65:21-66:15; 71:11-18; 72:21-74:1	H
Swamy, Sajani		R, 403, V, F, O, SPEC, PK, CP	41:6-8; 64:8-11; 64:13-65:4; 65:21-66:15; 71:11-18; 72:21-74:1	H
Swamy, Sajani		R, 403, V, F, O, SPEC, PK, CP	41:6-8; 64:8-11; 64:13-65:4; 65:21-66:15; 71:11-18; 72:21-74:1	Н
Swamy, Sajani		R, 403, V, F, O, PK, SPEC		+
Swamy, Sajani		R, 403, V, F, O, PK, SPEC		
Swamy, Sajani		R, 403, V, F, O, PK, SPEC		
Swamy, Sajani		R, 403, V, F, O, PK, SPEC		
Swamy, Sajani		R, 403, V, F, O, PK, SPEC		
Swamy, Sajani		R, 403, V, F, O, PK, SPEC		
Swamy, Sajani		R, 403, V, F, O, PK, SPEC		
Swamy, Sajani		R, 403, V, F, O, PK, SPEC		
	078:21-079:05	R, 403, V, F, O, PK, SPEC	79:7-19	Н
Swamy, Sajani	000 07 000 04	R, 403, V, F, O, PK, SPEC, MIS		
Swamy, Sajani Swamy, Sajani	080:07-080:24			
		R, 403, V, F, O, PK, SPEC, MIS		
Swamy, Sajani	081:01-081:01	R, 403, V, F, O, PK, SPEC, MIS R, 403, V, F, O, PK, SPEC		
Swamy, Sajani Swamy, Sajani Swamy, Sajani	081:01-081:01			
Swamy, Sajani Swamy, Sajani	081:01-081:01 081:03-081:05			

Swamy, Sajani 084:25-085:01 R Swamy, Sajani 086:02-086:11 R Swamy, Sajani 086:13-086:13 R Swamy, Sajani 090:18-190:12 R Swamy, Sajani 090:08-090:12 R Swamy, Sajani 090:20-091:17 R Swamy, Sajani 093:17-093:21 R Swamy, Sajani 093:25-094:07 J Swamy, Sajani 094:09-094:13 R Swamy, Sajani 095:09-095:15 R Swamy, Sajani 095:09-095:15 S Swamy, Sajani 096:06-096:13 R Swamy, Sajani 096:04-097:02 R Swamy, Sajani 097:04-097:05 F Swamy, Sajani 097:07-097:09 R Swamy, Sajani 097:17-098:16 F Swamy, Sajani 097:17-099:15 F Swamy, Sajani 099:17-099:25 F Swamy, Sajani 099:17-099:25 F Swamy, Sajani 100:02-100:07 F Swamy, Sajani	I, R, 403, O, PK, SPEC, V R, 403, O, PK, SPEC, V R, 403, O, PK, SPEC, V	82:20-83:3; 84:3-17 82:20-83:3; 84:3-17 89:12-90:7 89:12-90:7 89:12-90:7	H H
Swamy, Sajani 086:02-086:11 R Swamy, Sajani 086:13-086:13 R Swamy, Sajani 086:15-087:10 R Swamy, Sajani 090:08-090:12 R Swamy, Sajani 090:01-090:13 R Swamy, Sajani 093:25-094:07 J Swamy, Sajani 093:25-094:07 J Swamy, Sajani 094:09-094:13 R Swamy, Sajani 094:09-095:15 F Swamy, Sajani 095:05-096:13 R Swamy, Sajani 096:06-096:13 S Swamy, Sajani 096:04-097:02 F Swamy, Sajani 097:07-097:09 S Swamy, Sajani 097:07-097:09 F Swamy, Sajani 097:17-098:16 F Swamy, Sajani 097:17-099:15 F Swamy, Sajani 099:12-099:15 F Swamy, Sajani 099:12-099:15 F Swamy, Sajani 100:02-100:15 F Swamy, Sajani 100:02-100:15 F Swamy, Sajani	R, 403, V, PK, SPEC R, 403, V, PK, SPEC R, 403, V, PK, SPEC R, 403, V, O, PK, SPEC R, 403, V, MIS I, R, 403, O, PK, SPEC, V	89:12-90:7 89:12-90:7	
Swamy, Sajani 086:13-086:13 R Swamy, Sajani 086:15-087:10 R Swamy, Sajani 090:08-090:12 R Swamy, Sajani 090:14-090:18 R Swamy, Sajani 090:12-091:17 R Swamy, Sajani 093:17-093:21 R Swamy, Sajani 093:17-093:21 R Swamy, Sajani 094:09-094:13 R Swamy, Sajani 095:09-095:15 R Swamy, Sajani 095:09-095:15 R Swamy, Sajani 096:15-096:22 R Swamy, Sajani 096:15-096:22 R Swamy, Sajani 097:04-097:05 R Swamy, Sajani 097:07-097:09 R Swamy, Sajani 097:12-097:15 R Swamy, Sajani 097:17-098:16 R Swamy, Sajani 099:17-099:25 R Swamy, Sajani 100:02-100:07 R Swamy, Sajani 100:02-100:07 R Swamy, Sajani 100:02-100:07 R Swamy, Sajani	R, 403, V, PK, SPEC R, 403, V, PK, SPEC R, 403, V, O, PK, SPEC R, 403, V, MIS I, R, 403, O, PK, SPEC, V R, 403, O, PK, SPEC, V R, 403, O, PK, SPEC, V	89:12-90:7	
Swamy, Sajani 086:15-087:10 R Swamy, Sajani 090:08-090:12 R Swamy, Sajani 090:14-090:18 R Swamy, Sajani 090:20-091:17 R Swamy, Sajani 093:25-094:07 L Swamy, Sajani 094:15-095:07 S Swamy, Sajani 094:15-095:07 S Swamy, Sajani 095:09-095:15 F Swamy, Sajani 096:26-096:12 F Swamy, Sajani 096:26-096:12 S Swamy, Sajani 096:24-097:02 F Swamy, Sajani 097:07-097:09 F Swamy, Sajani 097:12-097:15 F Swamy, Sajani 097:17-098:16 F Swamy, Sajani 099:12-099:15 F Swamy, Sajani 099:12-099:15 F Swamy, Sajani 099:12-099:15 F Swamy, Sajani 100:02-100:07 F Swamy, Sajani 100:02-100:07 F Swamy, Sajani 100:02-100:07 F Swamy, Sajani	R, 403, V, PK, SPEC R, 403, V, O, PK, SPEC R, 403, V, O, PK, SPEC R, 403, V, O, PK, SPEC R, 403, V, MIS I, R, 403, O, PK, SPEC, V	89:12-90:7	
Swamy, Sajani 090:08-090:12 R Swamy, Sajani 090:14-090:18 R Swamy, Sajani 090:20-091:7 R Swamy, Sajani 093:17-093:21 R Swamy, Sajani 093:25-094:07 J Swamy, Sajani 094:15-095:07 J Swamy, Sajani 095:09-095:15 R Swamy, Sajani 096:06-096:13 R Swamy, Sajani 096:06-096:13 R Swamy, Sajani 096:04-097:02 R Swamy, Sajani 097:04-097:05 R Swamy, Sajani 097:04-097:05 R Swamy, Sajani 097:07-097:09 R Swamy, Sajani 097:17-098:16 R Swamy, Sajani 097:17-098:16 R Swamy, Sajani 099:17-099:25 R Swamy, Sajani 099:17-099:25 R Swamy, Sajani 099:17-099:25 R Swamy, Sajani 099:17-099:25 R Swamy, Sajani 100:02-100:07 S Swamy, Sajani 100:02-100:07 S Swamy, Sajani 100:20-100:15 R Swamy, Sajani 100:20-100:07 S Swamy, Sajani 100:20-100:07 S Swamy, Sajani 1	R, 403, V, O, PK, SPEC R, 403, V, O, PK, SPEC R, 403, V, O, PK, SPEC R, 403, V, MIS I, R, 403, O, PK, SPEC, V	89:12-90:7	
Swamy, Sajani 090:14-090:18 R Swamy, Sajani 090:20-091:17 R Swamy, Sajani 093:17-093:21 R Swamy, Sajani 093:17-093:21 R Swamy, Sajani 094:15-095:07 F Swamy, Sajani 095:09-095:15 F Swamy, Sajani 096:06-096:13 R Swamy, Sajani 096:15-096:22 F Swamy, Sajani 097:07-097:09 F Swamy, Sajani 097:07-097:09 F Swamy, Sajani 097:12-097:15 F Swamy, Sajani 097:17-098:16 F Swamy, Sajani 099:17-099:15 F Swamy, Sajani 099:12-099:15 F Swamy, Sajani 100:02-100:07 F Swamy, Sajani	R, 403, V, O, PK, SPEC R, 403, V, O, PK, SPEC R, 403, V, MIS I, R, 403, O, PK, SPEC, V R, 403, O, PK, SPEC, V R, 403, O, PK, SPEC, V	89:12-90:7	Н
Swamy, Sajani 090:20-091:17 R Swamy, Sajani 093:17-093:21 R Swamy, Sajani 093:25-094:07 J Swamy, Sajani 094:09-094:13 R Swamy, Sajani 095:09-095:15 R Swamy, Sajani 095:09-095:15 R Swamy, Sajani 096:06-096:12 R Swamy, Sajani 096:15-096:22 R Swamy, Sajani 097:04-097:05 R Swamy, Sajani 097:07-097:09 R Swamy, Sajani 097:12-097:15 R Swamy, Sajani 097:17-098:16 R Swamy, Sajani 099:12-099:15 S Swamy, Sajani 099:17-099:25 R Swamy, Sajani 100:02-100:07 R Swamy, Sajani	R, 403, V, O, PK, SPEC R, 403, V, MIS I, R, 403, O, PK, SPEC, V R, 403, O, PK, SPEC, V R, 403, O, PK, SPEC, V		H
Swamy, Sajani 093:17-093:21 R Swamy, Sajani 093:25-094:07 J Swamy, Sajani 094:09-094:13 R Swamy, Sajani 094:09-095:15 R Swamy, Sajani 095:09-095:15 R Swamy, Sajani 096:06-096:13 R Swamy, Sajani 096:24-097:02 R Swamy, Sajani 097:07-097:09 R Swamy, Sajani 097:07-097:09 R Swamy, Sajani 097:12-097:15 R Swamy, Sajani 097:12-099:15 R Swamy, Sajani 099:12-099:15 R Swamy, Sajani 099:12-099:15 R Swamy, Sajani 100:02-100:07 R Swamy, Sajani	R, 403, V, MIS I, R, 403, O, PK, SPEC, V R, 403, O, PK, SPEC, V R, 403, O, PK, SPEC, V	05:12 50:7	Н
Swamy, Sajani 093:25-094:07 J. Swamy, Sajani 094:09-094:13 R Swamy, Sajani 094:15-095:07 R Swamy, Sajani 095:09-095:15 R Swamy, Sajani 096:06-096:13 R Swamy, Sajani 096:06-096:13 R Swamy, Sajani 096:04-097:02 R Swamy, Sajani 097:04-097:05 R Swamy, Sajani 097:07-097:09 R Swamy, Sajani 097:17-098:16 R Swamy, Sajani 097:17-099:15 R Swamy, Sajani 099:17-099:25 R Swamy, Sajani 099:17-099:25 R Swamy, Sajani 099:17-099:25 R Swamy, Sajani 100:02-100:07 S Swamy, Sajani 100:02-100:07 S Swamy, Sajani 100:20-100:15 R	I, R, 403, O, PK, SPEC, V R, 403, O, PK, SPEC, V R, 403, O, PK, SPEC, V		BSD, H
Swamy, Sajani 094:09-094:13 R Swamy, Sajani 094:05-095:07 R Swamy, Sajani 095:09-095:15 R Swamy, Sajani 096:06-096:13 R Swamy, Sajani 096:04-097:02 R Swamy, Sajani 097:04-097:05 R Swamy, Sajani 097:07-097:09 S Swamy, Sajani 097:17-098:16 S Swamy, Sajani 097:17-098:16 S Swamy, Sajani 099:12-099:15 S Swamy, Sajani 099:12-099:15 S Swamy, Sajani 100:02-100:07 S Swamy, Sajani 100:02-100:15 S Swamy, Sajani 100:02-100:15 S Swamy, Sajani 100:02-100:15 S Swamy, Sajani 100:02-100:15 S Swamy, Sajani 100:02-100:16 S Swamy, Sajani 104:02-104:06 S Swamy, Sajani 104:02-104:06 S Swamy, Sajani 104:12-104:10 S Swamy, Sajani	R, 403, O, PK, SPEC, V R, 403, O, PK, SPEC, V	101:2-14; 101:16-20; 102:17-103:19	BSD, H
Swamy, Sajani 094:15-095:07 R Swamy, Sajani 095:09-095:15 R Swamy, Sajani 096:06-096:13 R Swamy, Sajani 096:06-096:12 R Swamy, Sajani 096:15-096:22 R Swamy, Sajani 097:04-097:05 R Swamy, Sajani 097:07-097:09 R Swamy, Sajani 097:12-097:15 R Swamy, Sajani 099:12-099:15 S Swamy, Sajani 099:17-099:25 R Swamy, Sajani 100:02-100:07 R Swamy, Sajani 100:02-100:07 R Swamy, Sajani 100:20-100:15 R Swamy, Sajani 100:20-100:22 R Swamy, Sajani 104:02-104:04 R Swamy, Sajani 104:02-104:04 R Swamy, Sajani 104:02-104:04 R Swamy, Sajani 104:12-104:13 R Swamy, Sajani 104:12-104:13 R Swamy, Sajani 101:19-110:24 R Swamy, Sajani	R, 403, O, PK, SPEC, V	101:2-14; 101:16-20; 102:17-103:19	BSD, H
Swamy, Sajani 095:09-095:15 R Swamy, Sajani 096:06-096:13 R Swamy, Sajani 096:15-096:22 R Swamy, Sajani 096:24-097:02 R Swamy, Sajani 097:07-097:09 R Swamy, Sajani 097:12-097:15 R Swamy, Sajani 097:17-098:16 R Swamy, Sajani 099:12-099:15 R Swamy, Sajani 099:17-099:25 R Swamy, Sajani 100:02-100:07 R Swamy, Sajani 100:02-100:07 R Swamy, Sajani 100:09-100:15 R Swamy, Sajani 100:09-100:15 R Swamy, Sajani 100:02-100:07 R Swamy, Sajani 100:02-100:07 R Swamy, Sajani 100:09-100:15 R Swamy, Sajani 100:20-100:07 R Swamy, Sajani 104:02-100:04 R Swamy, Sajani 104:02-100:04 R Swamy, Sajani 104:02-104:04 R Swamy, Sajani		101:2-14; 101:16-20; 102:17-103:19	BSD, H
Swamy, Sajani 096:06-096:13 R Swamy, Sajani 096:15-096:22 R Swamy, Sajani 096:24-097:02 R Swamy, Sajani 097:04-097:05 R Swamy, Sajani 097:07-097:09 R Swamy, Sajani 097:17-098:16 R Swamy, Sajani 099:17-099:15 R Swamy, Sajani 099:17-099:25 R Swamy, Sajani 099:17-099:25 R Swamy, Sajani 100:02-100:07 R Swamy, Sajani 100:02-100:07 R Swamy, Sajani 103:20-103:22 R Swamy, Sajani 103:20-103:22 R Swamy, Sajani 104:02-104:04 R Swamy, Sajani 104:02-104:06 R Swamy, Sajani 104:02-104:06 R Swamy, Sajani 104:12-104:13 R Swamy, Sajani 104:12-104:20 R Swamy, Sajani 104:12-104:24 R Swamy, Sajani 110:19-110:24 R Swamy, Sajani	11, TOU, U, FR, JFLC, V	101:2-14; 101:16-20; 102:17-103:19	BSD, H
Swamy, Sajani 096:24-097:02 R Swamy, Sajani 097:07-097:09 R Swamy, Sajani 097:07-097:09 R Swamy, Sajani 097:17-098:16 R Swamy, Sajani 099:17-099:15 R Swamy, Sajani 099:12-099:15 R Swamy, Sajani 099:17-099:25 R Swamy, Sajani 100:02-100:07 R Swamy, Sajani 100:02-100:07 R Swamy, Sajani 100:20-100:15 R Swamy, Sajani 100:20-100:15 R Swamy, Sajani 103:20-103:25 R Swamy, Sajani 104:02-104:04 R Swamy, Sajani 104:02-104:04 R Swamy, Sajani 104:08-104:10 R Swamy, Sajani 104:12-104:13 R Swamy, Sajani 104:12-104:13 R Swamy, Sajani 104:12-104:13 R Swamy, Sajani 110:19-110:24 R Swamy, Sajani 111:02-111:03 R Swamy, Sajani	R, 403, O, PK, SPEC, V	101:2-14; 101:16-20; 102:17-103:19	BSD, H
Swamy, Sajani 097:04-097:05 R Swamy, Sajani 097:07-097:09 R Swamy, Sajani 097:12-097:15 R Swamy, Sajani 099:12-099:16 R Swamy, Sajani 099:12-099:15 R Swamy, Sajani 099:17-099:25 R Swamy, Sajani 100:02-100:07 S Swamy, Sajani 100:02-100:07 S Swamy, Sajani 100:20-100:22 R Swamy, Sajani 100:20-100:22 R Swamy, Sajani 104:02-104:04 R Swamy, Sajani 104:02-104:04 R Swamy, Sajani 104:02-104:04 R Swamy, Sajani 104:12-104:13 R Swamy, Sajani 104:12-104:13 R Swamy, Sajani 104:12-104:13 R Swamy, Sajani 104:12-104:20 R Swamy, Sajani 110:19-110:24 R Swamy, Sajani 110:19-110:24 R Swamy, Sajani 111:07-111:03 R Swamy, Sajani	R, 403, O, PK, SPEC, V	101:2-14; 101:16-20; 102:17-103:19	BSD, H
Swamy, Sajani 097:07-097:09 F Swamy, Sajani 097:17-098:16 F Swamy, Sajani 097:17-098:16 F Swamy, Sajani 099:17-099:15 F Swamy, Sajani 099:17-099:25 F Swamy, Sajani 100:02-100:07 F Swamy, Sajani 100:02-100:15 F Swamy, Sajani 103:20-103:22 F Swamy, Sajani 103:20-103:22 F Swamy, Sajani 104:02-104:04 F Swamy, Sajani 104:02-104:06 F Swamy, Sajani 104:02-104:06 F Swamy, Sajani 104:12-104:13 F Swamy, Sajani 104:12-104:20 F Swamy, Sajani 104:12-104:24 F Swamy, Sajani 110:19-110:24 F Swamy, Sajani 111:07-111:03 S Swamy, Sajani 111:07-111:03 S Swamy, Sajani 111:07-111:03 S Swamy, Sajani 111:07-111:03 S Swamy, Sajani	R, 403, O, PK, SPEC, V	101:2-14; 101:16-20; 102:17-103:19	BSD, H
Swamy, Sajani 097:12-097:15 R Swamy, Sajani 097:17-098:16 R Swamy, Sajani 099:12-099:15 R Swamy, Sajani 099:12-099:15 R Swamy, Sajani 099:17-099:25 R Swamy, Sajani 100:09-100:17 R Swamy, Sajani 100:20-100:22 R Swamy, Sajani 103:20-103:22 S Swamy, Sajani 104:02-104:04 R Swamy, Sajani 104:06-104:06 R Swamy, Sajani 104:12-104:10 R Swamy, Sajani 104:12-104:24 R Swamy, Sajani 104:12-104:24 R Swamy, Sajani 104:12-104:24 R Swamy, Sajani 110:19-110:24 R Swamy, Sajani 110:19-110:24 R Swamy, Sajani 111:07-111:09 S Swamy, Sajani 111:17-112:07 R Swamy, Sajani 111:17-112:07 R Swamy, Sajani 111:17-112:07 R Swamy, Sajani	R, 403, O, PK, SPEC, V	101:2-14; 101:16-20; 102:17-103:19	BSD, H
Swamy, Sajani 097:17-098:16 F Swamy, Sajani 098:18-098:20 F Swamy, Sajani 099:12-099:15 F Swamy, Sajani 100:02-100:07 F Swamy, Sajani 100:02-100:15 F Swamy, Sajani 100:20-100:25 F Swamy, Sajani 103:20-103:25 F Swamy, Sajani 104:02-104:04 F Swamy, Sajani 104:02-104:04 F Swamy, Sajani 104:08-104:10 F Swamy, Sajani 104:12-104:13 F Swamy, Sajani 111:02-111:02 F Swamy, Sajani 111:02-111:03 S Swamy, Sajani 111:02-111:03 S Swamy, Sajani	R, 403, O, PK, SPEC, V	101:2-14; 101:16-20; 102:17-103:19	BSD, H
Swamy, Sajani 098:18-098:20 F Swamy, Sajani 099:12-099:15 F Swamy, Sajani 099:17-099:25 F Swamy, Sajani 100:02-100:07 F Swamy, Sajani 100:09-100:15 F Swamy, Sajani 103:24-103:25 F Swamy, Sajani 104:02-104:04 F Swamy, Sajani 104:08-104:10 F Swamy, Sajani 104:08-104:10 F Swamy, Sajani 104:12-104:13 F Swamy, Sajani 104:12-104:20 F Swamy, Sajani 104:12-104:24 F Swamy, Sajani 101:19-110:24 F Swamy, Sajani 111:02-111:03 S Swamy, Sajani 111:07-111:09 F Swamy, Sajani 111:17-111:07 R Swamy, Sajani 111:17-111:07 R Swamy, Sajani 111:07-111:09 R Swamy, Sajani 111:17-112:07 R Swamy, Sajani 111:17-112:07 R Swamy, Sajani	R, 403, O, PK, SPEC, V	101:2-14; 101:16-20; 102:17-103:19	BSD, H
Swamy, Sajani 099:12-099:15 F Swamy, Sajani 099:17-099:25 F Swamy, Sajani 100:02-100:07 F Swamy, Sajani 100:09-100:15 F Swamy, Sajani 103:20-103:22 F Swamy, Sajani 104:02-104:04 F Swamy, Sajani 104:02-104:06 F Swamy, Sajani 104:02-104:06 F Swamy, Sajani 104:12-104:13 F Swamy, Sajani 104:12-104:24 F Swamy, Sajani 104:12-104:24 F Swamy, Sajani 110:19-110:24 R Swamy, Sajani 111:07-111:03 S Swamy, Sajani 111:07-111:03 S Swamy, Sajani 111:107-111:03 R Swamy, Sajani <td>R, 403, O, PK, SPEC, V</td> <td>101:2-14; 101:16-20; 102:17-103:19</td> <td>BSD, H</td>	R, 403, O, PK, SPEC, V	101:2-14; 101:16-20; 102:17-103:19	BSD, H
Swamy, Sajani 099:17-099:25 R Swamy, Sajani 100:02-100:07 R Swamy, Sajani 100:09-100:15 R Swamy, Sajani 103:20-103:22 R Swamy, Sajani 104:02-104:04 R Swamy, Sajani 104:06-104:06 R Swamy, Sajani 104:06-104:10 R Swamy, Sajani 104:12-104:13 R Swamy, Sajani 104:12-104:24 R Swamy, Sajani 104:19-10:24 R Swamy, Sajani 110:19-110:24 R Swamy, Sajani 111:07-111:09 Swamy, Sajani Swamy, Sajani 111:17-112:07 R Swamy, Sajani 116:03-116:08 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 116:10-116:14 R Swamy, Sajan	R, 403, O, PK, SPEC, V	101:2-14; 101:16-20; 102:17-103:19	BSD, H
Swamy, Sajani 100:02-100:07 F Swamy, Sajani 100:09-100:15 F Swamy, Sajani 103:20-103:22 F Swamy, Sajani 103:24-103:25 F Swamy, Sajani 104:02-104:04 F Swamy, Sajani 104:08-104:10 F Swamy, Sajani 104:12-104:13 F Swamy, Sajani 104:12-104:13 F Swamy, Sajani 104:12-104:14 F Swamy, Sajani 104:12-104:24 F Swamy, Sajani 110:19-110:24 F Swamy, Sajani 111:07-111:09 Swamy, Sajani Swamy, Sajani 111:07-111:09 Swamy, Sajani 111:17-111:07 Swamy, Sajani 111:17-111:02 R Swamy, Sajani 111:17-111:02 R Swamy, Sajani 111:07-111:02 R Swamy, Sajani 116:04-116:14 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 116:16-16:21 R Swamy, Sajani 117:14-118:15 S	R, 403, O, PK, SPEC, V	101:2-14; 101:16-20; 102:17-103:19	BSD, H
Swamy, Sajani 100:09-100:15 F Swamy, Sajani 103:20-103:22 F Swamy, Sajani 103:24-103:25 F Swamy, Sajani 104:02-104:04 F Swamy, Sajani 104:08-104:10 F Swamy, Sajani 104:12-104:13 F Swamy, Sajani 104:12-104:20 F Swamy, Sajani 100:19-110:24 F Swamy, Sajani 111:02-111:03 F Swamy, Sajani 111:07-111:09 F Swamy, Sajani 111:10-111:09 F Swamy, Sajani 111:10-111:09 F Swamy, Sajani 111:17-111:07 R Swamy, Sajani 111:17-112:07 R Swamy, Sajani 115:04-115:24 R Swamy, Sajani 115:04-115:24 R Swamy, Sajani 116:01-116:14 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 116:16-116:21 R Swamy, Sajani 117:05-117:06 F Swamy, Sajani	R, 403, O, PK, SPEC, V	101:2-14; 101:16-20; 102:17-103:19	BSD, H
Swamy, Sajani 103:20-103:22 F Swamy, Sajani 103:24-103:25 F Swamy, Sajani 104:02-104:04 F Swamy, Sajani 104:06-104:06 F Swamy, Sajani 104:12-104:13 F Swamy, Sajani 104:12-104:20 F Swamy, Sajani 104:22-104:24 F Swamy, Sajani 110:19-110:24 R Swamy, Sajani 111:07-111:03 Swamy, Sajani Swamy, Sajani 111:07-111:03 Swamy, Sajani Swamy, Sajani 111:17-112:07 R Swamy, Sajani 111:17-112:07 R Swamy, Sajani 111:17-112:07 R Swamy, Sajani 115:04-115:24 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 116:16-116:21 R Swamy, Sajani 117:05-117:06 S Swamy, Sajani 117:14-118:15 R Swamy, Sajani 112:01-12:13 R		101:2-14; 101:16-20; 102:17-103:19	BSD, H
Swamy, Sajani 103:24-103:25 R Swamy, Sajani 104:06-104:06 R Swamy, Sajani 104:06-104:10 R Swamy, Sajani 104:12-104:13 R Swamy, Sajani 104:12-104:24 R Swamy, Sajani 104:12-104:24 R Swamy, Sajani 110:19-110:24 R Swamy, Sajani 111:07-111:09 Swamy, Sajani Swamy, Sajani 111:07-111:09 Swamy, Sajani Swamy, Sajani 111:17-112:07 R Swamy, Sajani 111:17-112:07 R Swamy, Sajani 111:04-115:24 R Swamy, Sajani 111:04-115:24 R Swamy, Sajani 116:03-116:08 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 117:05-117:06 R Swamy, Sajani 117:14-118:15 R Swamy, Sajani 117:14-118:15 R Swamy, Sajani 122:06-122:14 R <td< td=""><td></td><td>101:2-14; 101:16-20; 102:17-103:19</td><td>BSD, H</td></td<>		101:2-14; 101:16-20; 102:17-103:19	BSD, H
Swamy, Sajani 104:02-104:04 R Swamy, Sajani 104:08-104:10 R Swamy, Sajani 104:08-104:10 R Swamy, Sajani 104:12-104:13 R Swamy, Sajani 104:12-104:24 R Swamy, Sajani 104:12-104:24 R Swamy, Sajani 110:19-110:24 R Swamy, Sajani 111:07-111:09 Swamy, Sajani Swamy, Sajani 111:17-111:07 Swamy, Sajani Swamy, Sajani 111:17-112:07 R Swamy, Sajani 111:17-112:02 R Swamy, Sajani 111:07-111:02 R Swamy, Sajani 111:07-115:02 R Swamy, Sajani 111:07-115:02 R Swamy, Sajani 116:03-116:08 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 117:05-117:06 S Swamy, Sajani 117:14-118:15 R Swamy, Sajani 112:07-12:13 R Swamy, Sajani 122:07-12:14 R S	R, 403, O, PK, SPEC, V, LC	101:2-14; 101:16-20; 102:17-103:19; 106:2-4; 106:13-18; 107:17-110:18	BSD, H BSD, H
Swamy, Sajani 104:06-104:06 F Swamy, Sajani 104:08-104:10 F Swamy, Sajani 104:12-104:13 F Swamy, Sajani 104:12-104:20 F Swamy, Sajani 104:22-104:24 F Swamy, Sajani 111:02-111:03 F Swamy, Sajani 111:07-111:09 S Swamy, Sajani 111:17-111:09 F Swamy, Sajani 111:17-111:07 R Swamy, Sajani 111:17-112:07 R Swamy, Sajani 115:04-115:24 R Swamy, Sajani 115:04-115:24 R Swamy, Sajani 116:01-116:14 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 116:16-116:21 R Swamy, Sajani 117:05-117:06 S Swamy, Sajani 117:05-117:06 S Swamy, Sajani 117:05-117:06 S Swamy, Sajani 112:07-712:13 R Swamy, Sajani 122:07-12:14 R Swamy, Sajani		101:2-14; 101:16-20; 102:17-103:19; 106:2-4; 106:13-18; 107:17-110:18 101:2-14; 101:16-20; 102:17-103:19; 106:2-4; 106:13-18; 107:17-110:18	BSD, H
Swamy, Sajani 104:08-104:10 F Swamy, Sajani 104:12-104:13 F Swamy, Sajani 104:12-104:24 F Swamy, Sajani 110:19-110:24 R Swamy, Sajani 111:07-111:09 Swamy, Sajani Swamy, Sajani 111:07-111:09 Swamy, Sajani 111:17-112:07 R Swamy, Sajani 111:17-112:07 R Swamy, Sajani 111:17-112:07 R Swamy, Sajani 111:17-112:07 R Swamy, Sajani 115:04-115:24 R Swamy, Sajani 116:03-116:08 R Swamy, Sajani 116:04-116:14 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 116:16-116:21 R Swamy, Sajani 117:05-117:06 Swamy, Sajani 117:14-118:15 R Swamy, Sajani 117:14-118:15 R Swamy, Sajani 120:07-121:13 R Swamy, Sajani 117:14-118:15 R Swamy, Sajani 122:02-122:14 R Swamy, Sajani 122:01-122:13 R Swamy, Sajani		101:2-14; 101:16-20; 102:17-103:19; 106:2-4; 106:13-18; 107:17-110:18	BSD, H
Swamy, Sajani 104:12-104:13 R Swamy, Sajani 104:15-104:20 R Swamy, Sajani 104:22-104:24 R Swamy, Sajani 110:19-110:24 R Swamy, Sajani 111:07-111:09 Swamy, Sajani Swamy, Sajani 111:17-112:07 R Swamy, Sajani 111:17-112:07 R Swamy, Sajani 115:04-115:24 R Swamy, Sajani 116:03-116:08 R Swamy, Sajani 116:03-116:04 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 117:05-117:06 S Swamy, Sajani 117:14-118:15 R Swamy, Sajani 112:00-122:14 R Swamy, Sajani 122:06-122:14 R Swamy, Sajani 122:16-123:03 R Swamy, Sajani 122:16-123:03 R Swamy, Sajani 123:18-123:22 R Swamy, Sajani 125:09-125:11 Swamy, Sajani 127:01-127:03		101:2-14; 101:16-20; 102:17-103:19; 106:2-4; 106:13-18; 107:17-110:18	BSD, H
Swamy, Sajani 104:15-104:20 R Swamy, Sajani 104:22-104:24 R Swamy, Sajani 110:19-110:24 R Swamy, Sajani 111:02-111:03 Swamy, Sajani 111:07-111:09 Swamy, Sajani 111:17-111:07 Swamy, Sajani 111:17-112:07 Swamy, Sajani 111:02-113:02 Swamy, Sajani 116:03-116:08 Swamy, Sajani 116:10-116:14 Swamy, Sajani 116:10-116:14 Swamy, Sajani 116:16-116:21 Swamy, Sajani 117:05-117:06 Swamy, Sajani 117:14-118:15 Swamy, Sajani 120:07-121:13 Swamy, Sajani 122:02-122:14 Swamy, Sajani 122:02-123:08 Swamy, Sajani	R, 403, O, PK, SPEC, V	101:2-14; 101:16-20; 102:17-103:19; 106:2-4; 106:13-18; 107:17-110:18	BSD, H
Swamy, Sajani 104:22-104:24 R Swamy, Sajani 110:19-110:24 R Swamy, Sajani 111:02-111:03 S Swamy, Sajani 111:07-111:09 S Swamy, Sajani 111:17-111:07 R Swamy, Sajani 111:17-112:07 R Swamy, Sajani 111:04-115:24 R Swamy, Sajani 116:04-115:24 R Swamy, Sajani 116:04-116:04 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 116:16-116:25 R Swamy, Sajani 117:05-117:06 S Swamy, Sajani 117:05-117:06 S Swamy, Sajani 117:05-117:06 S Swamy, Sajani 122:07-12:13 R Swamy, Sajani 122:07-12:13 R Swamy, Sajani 122:16-123:03 R Swamy, Sajani 122:16-123:03 R Swamy, Sajani 122:16-123:03 R Swamy, Sajani 122:16-123:03 R Swamy, Sajani	R, 403, O, PK, SPEC, V, CP	101:2-14; 101:16-20; 102:17-103:19; 106:2-4; 106:13-18; 107:17-110:18	BSD, H
Swamy, Sajani 110:19-110:24 R Swamy, Sajani 111:07-111:09 Swamy, Sajani 111:07-111:09 Swamy, Sajani 111:17-112:07 R Swamy, Sajani 111:17-112:07 R Swamy, Sajani 115:04-115:24 R Swamy, Sajani 116:04-116:08 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 116:16-116:21 R Swamy, Sajani 117:05-117:06 S Swamy, Sajani 117:05-117:06 S Swamy, Sajani 120:07-121:13 R Swamy, Sajani 120:07-121:13 R Swamy, Sajani 122:02-122:14 R Swamy, Sajani 122:02-122:14 R Swamy, Sajani 123:05-123:16 R Swamy, Sajani 122:02-122:14 R Swamy, Sajani 122:02-122:14 R Swamy, Sajani 122:05-123:16 R Swamy, Sajani 125:18-126:01 S Swamy, Sajani 125:18-126:01 <td< td=""><td>R, 403, O, PK, SPEC, V, CP</td><td>101:2-14; 101:16-20; 102:17-103:19; 106:2-4; 106:13-18; 107:17-110:18</td><td>BSD, H</td></td<>	R, 403, O, PK, SPEC, V, CP	101:2-14; 101:16-20; 102:17-103:19; 106:2-4; 106:13-18; 107:17-110:18	BSD, H
Swamy, Sajani 111:02-111:03 Swamy, Sajani 111:07-111:09 Swamy, Sajani 111:13-11:15 Swamy, Sajani 111:17-112:07 Swamy, Sajani 112:22-113:02 Swamy, Sajani 115:04-115:24 Swamy, Sajani 116:03-116:08 Swamy, Sajani 116:10-116:14 Swamy, Sajani 116:10-116:21 Swamy, Sajani 117:05-117:06 Swamy, Sajani 117:05-117:06 Swamy, Sajani 117:01-117:06 Swamy, Sajani 117:14-118:15 Swamy, Sajani 122:02-122:14 Swamy, Sajani 122:16-123:03 Swamy, Sajani 122:16-123:03 Swamy, Sajani 123:18-123:22 Swamy, Sajani 125:09-125:11 Swamy, Sajani 127:01-127:03 Swamy, Sajani 127:01-127:03 Swamy, Sajani 127:05-127:19 Swamy, Sajani 129:15-129:21 Swamy, Sajani 129:15-129:21 Swamy, Sajani 130:04-130:13 Swamy, Sajani 133:07-133:18 <td< td=""><td>R, 403, O, PK, SPEC, V</td><td>106:2-4; 106:13-18; 107:17-110:18</td><td></td></td<>	R, 403, O, PK, SPEC, V	106:2-4; 106:13-18; 107:17-110:18	
Swamy, Sajani 111:07-111:09 Swamy, Sajani 111:13-111:15 Swamy, Sajani 111:17-112:07 Swamy, Sajani 111:22-113:02 Swamy, Sajani 115:04-115:24 Swamy, Sajani 116:03-116:08 Swamy, Sajani 116:10-116:14 Swamy, Sajani 116:10-116:12 Swamy, Sajani 117:05-117:06 Swamy, Sajani 117:05-117:06 Swamy, Sajani 117:01-118:15 Swamy, Sajani 120:07-121:13 Swamy, Sajani 122:02-122:14 Swamy, Sajani 122:02-122:14 Swamy, Sajani 123:05-123:16 Swamy, Sajani 123:05-123:16 Swamy, Sajani 125:09-125:11 Swamy, Sajani 125:09-125:11 Swamy, Sajani 127:01-127:03 Swamy, Sajani 127:05-127:19 Swamy, Sajani 129:15-129:21 Swamy, Sajani 129:23-130:02 Swamy, Sajani 133:07-133:18 Swamy, Sajani 133:07-133:18 Swamy, Sajani 133:07-133:18 <t< td=""><td><u>.,,, .,</u></td><td></td><td></td></t<>	<u>.,,, .,</u>		
Swamy, Sajani 111:17-112:07 R Swamy, Sajani 112:22-113:02 R Swamy, Sajani 115:04-115:24 R Swamy, Sajani 116:03-116:08 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 116:16-116:21 R Swamy, Sajani 117:05-117:06 Swamy, Sajani 117:05-117:06 Swamy, Sajani 120:07-121:13 R Swamy, Sajani 120:07-121:13 R Swamy, Sajani 122:16-123:03 R Swamy, Sajani 122:16-123:03 R Swamy, Sajani 123:05-123:16 R Swamy, Sajani 123:05-123:16 R Swamy, Sajani 125:09-125:11 S Swamy, Sajani 127:01-127:03 R Swamy, Sajani 127:01-127:03 R Swamy, Sajani 129:15-129:17 R Swamy, Sajani 129:15-129:17 R Swamy, Sajani 130:04-130:13 R Swamy, Sajani 133:07-133:18 R			
Swamy, Sajani 112:22-113:02 R Swamy, Sajani 115:04-115:24 R Swamy, Sajani 116:03-116:08 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 116:16-116:21 R Swamy, Sajani 117:05-117:06 S Swamy, Sajani 117:05-117:06 S Swamy, Sajani 120:07-121:13 R Swamy, Sajani 122:02-122:14 R Swamy, Sajani 122:02-122:14 R Swamy, Sajani 122:16-123:03 R Swamy, Sajani 123:18-123:22 R Swamy, Sajani 125:09-125:11 Swamy, Sajani 125:09-125:11 Swamy, Sajani 127:01-127:03 R Swamy, Sajani 127:05-127:19 R Swamy, Sajani 129:15-129:21 R Swamy, Sajani 129:15-129:21 R Swamy, Sajani 130:04-130:13 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 133:07-133:18 R			
Swamy, Sajani 115:04-115:24 R Swamy, Sajani 116:03-116:08 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 116:16-116:21 R Swamy, Sajani 117:05-117:06 S Swamy, Sajani 117:05-117:06 S Swamy, Sajani 117:14-118:15 S Swamy, Sajani 122:07-122:14 R Swamy, Sajani 122:06-123:03 R Swamy, Sajani 122:16-123:03 R Swamy, Sajani 123:18-123:22 R Swamy, Sajani 125:09-125:11 S Swamy, Sajani 125:09-125:11 S Swamy, Sajani 127:05-127:19 R Swamy, Sajani 129:15-129:21 R Swamy, Sajani 129:23-130:02 R Swamy, Sajani 130:04-130:13 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani	R, 403, V, PK, SPEC	112:9-21	Н
Swamy, Sajani 116:03-116:08 R Swamy, Sajani 116:10-116:14 R Swamy, Sajani 116:16-116:21 R Swamy, Sajani 117:05-117:06 Swamy, Sajani 117:05-117:06 Swamy, Sajani 117:04-118:15 R Swamy, Sajani 120:07-121:13 R Swamy, Sajani 122:02-122:14 R Swamy, Sajani 123:05-123:16 R Swamy, Sajani 123:05-123:16 R Swamy, Sajani 125:09-125:11 Swamy, Sajani 125:18-126:01 Swamy, Sajani 127:01-127:03 R Swamy, Sajani 127:05-127:19 R Swamy, Sajani 129:15-129:21 R Swamy, Sajani 130:04-130:13 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 141:11-142:08 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 145:19-146:09 R Swamy, Sajani 145:19	R, 403, PK, SPEC	112:9-21	Н
Swamy, Sajani 116:10-116:14 R Swamy, Sajani 116:16-116:21 R Swamy, Sajani 116:23-116:25 R Swamy, Sajani 117:05-117:06 Swamy, Sajani 117:14-118:15 R Swamy, Sajani 120:07-121:13 R Swamy, Sajani 122:02-122:14 R Swamy, Sajani 122:16-123:03 R Swamy, Sajani 123:05-123:16 R Swamy, Sajani 123:05-123:16 R Swamy, Sajani 125:09-125:11 Swamy, Sajani 125:09-125:11 Swamy, Sajani 127:01-127:03 R Swamy, Sajani 127:01-127:03 R Swamy, Sajani 127:01-127:03 R Swamy, Sajani 129:15-129:17 R Swamy, Sajani 129:15-129:17 R Swamy, Sajani 130:04-130:13 R Swamy, Sajani 130:04-130:13 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 141:11-142:08 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 145:09-145:17 R Swamy, Sajani 146:10-146:19 R Swamy, Sajani	R, 403, I, PK, SPEC, O		
Swamy, Sajani 116:16-116:21 R Swamy, Sajani 116:23-116:25 R Swamy, Sajani 117:05-117:06 R Swamy, Sajani 117:14-118:15 R Swamy, Sajani 122:07-121:13 R Swamy, Sajani 122:06-123:03 R Swamy, Sajani 122:16-123:03 R Swamy, Sajani 123:18-123:22 R Swamy, Sajani 125:09-125:11 Swamy, Sajani 125:09-125:11 Swamy, Sajani 127:01-127:03 R Swamy, Sajani 127:05-127:19 R Swamy, Sajani 129:15-129:21 R Swamy, Sajani 130:04-130:13 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 145:19-146:19 R Swamy, Sajani 145:19-146:19 R Swamy, Sajani 146:11-146:12 R	R, 403, PK, SPEC, O		
Swamy, Sajani 116:23-116:25 R Swamy, Sajani 117:05-117:06 R Swamy, Sajani 117:14-118:15 R Swamy, Sajani 120:07-121:13 R Swamy, Sajani 122:02-122:14 R Swamy, Sajani 122:16-123:03 R Swamy, Sajani 123:05-123:16 R Swamy, Sajani 125:09-125:11 Swamy, Sajani 125:09-125:11 Swamy, Sajani 127:00-127:03 R Swamy, Sajani 127:05-127:19 R Swamy, Sajani 129:15-129:21 R Swamy, Sajani 129:23-130:02 R Swamy, Sajani 130:04-130:13 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 145:19-146:09 R Swamy, Sajani 146:11-146:19 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:17-146:19 R	R, 403, PK, SPEC, O		
Swamy, Sajani 117:05-117:06 Swamy, Sajani 117:14-118:15 Swamy, Sajani 120:07-121:13 Swamy, Sajani 122:02-122:14 Swamy, Sajani 122:16-123:03 Swamy, Sajani 123:05-123:16 Swamy, Sajani 123:18-123:22 Swamy, Sajani 125:09-125:11 Swamy, Sajani 125:09-125:11 Swamy, Sajani 127:01-127:03 Swamy, Sajani 127:05-127:19 Swamy, Sajani 129:15-129:21 Swamy, Sajani 130:04-130:13 Swamy, Sajani 133:07-133:18 Swamy, Sajani 133:07-133:18 Swamy, Sajani 141:11-142:08 Swamy, Sajani 142:10-142:10 Swamy, Sajani 145:19-146:09 Swamy, Sajani 145:19-146:19 Swamy, Sajani 146:11-146:12 Swamy, Sajani 146:11-146:15 Swamy, Sajani 146:17-146:19 Swamy, Sajani 146:17-146:19 Swamy, Sajani 146:17-146:19 Swamy, Sajani 146:17-146:19			
Swamy, Sajani 117:14-118:15 R Swamy, Sajani 120:07-121:13 R Swamy, Sajani 122:02-122:14 R Swamy, Sajani 122:16-123:03 R Swamy, Sajani 123:05-123:16 R Swamy, Sajani 123:18-123:22 R Swamy, Sajani 125:09-125:11 Swamy, Sajani 125:18-126:01 Swamy, Sajani 127:01-127:03 R Swamy, Sajani 127:01-127:09 R Swamy, Sajani 129:15-129:21 R Swamy, Sajani 130:04-130:13 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 141:11-142:08 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 145:09-145:17 R Swamy, Sajani 146:10-146:19 R Swamy, Sajani 146:11-146:12 R Swamy, Sajani 146:11-146:19 R Swamy, Sajani 146:17-146:19 R	R, 403, PK, SPEC, O		
Swamy, Sajani 120:07-121:13 R Swamy, Sajani 122:02-122:14 R Swamy, Sajani 122:16-123:03 R Swamy, Sajani 123:05-123:16 R Swamy, Sajani 123:09-125:11 Swamy, Sajani 125:09-125:11 Swamy, Sajani 127:01-127:03 R Swamy, Sajani 127:01-127:03 R Swamy, Sajani 129:15-129:21 R Swamy, Sajani 129:23-130:02 R Swamy, Sajani 130:04-130:13 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 143:11-142:08 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 145:19-146:17 R Swamy, Sajani 146:11-146:12 R Swamy, Sajani 146:11-146:19 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:17-146:19 R	2 402 1/		
Swamy, Sajani 122:02-122:14 R Swamy, Sajani 122:16-123:03 R Swamy, Sajani 123:05-123:16 R Swamy, Sajani 123:18-123:22 R Swamy, Sajani 125:09-125:11 Swamy, Sajani 125:09-125:11 Swamy, Sajani 127:01-127:03 R Swamy, Sajani 129:10-127:03 R Swamy, Sajani 129:15-129:21 R Swamy, Sajani 130:04-130:13 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 133:22-135:11 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 145:19-146:09 R Swamy, Sajani 146:11-146:12 R Swamy, Sajani 146:11-146:19 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:17-146:19 R		121/14 122/4	DCD II
Swamy, Sajani 122:16-123:03 R Swamy, Sajani 123:05-123:16 R Swamy, Sajani 123:18-123:22 R Swamy, Sajani 125:09-125:11 Swamy, Sajani 125:18-126:01 Swamy, Sajani 127:01-127:03 R Swamy, Sajani 127:05-127:19 R Swamy, Sajani 129:15-129:21 R Swamy, Sajani 130:04-130:13 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 133:22-135:11 R Swamy, Sajani 141:11-142:08 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 145:19-146:09 R Swamy, Sajani 146:11-146:12 R Swamy, Sajani 146:11-146:15 R Swamy, Sajani 146:11-146:15 R Swamy, Sajani 146:11-146:19 R Swamy, Sajani 146:11-146:19 R Swamy, Sajani 146:12-146:19 R Swamy, Sajani 146:12-146:19 R <		121:14-122:1 121:14-122:1	BSD, H BSD, H
Swamy, Sajani 123:05-123:16 R Swamy, Sajani 123:18-123:22 R Swamy, Sajani 125:09-125:11 Swamy, Sajani 125:18-126:01 Swamy, Sajani 127:01-127:03 R Swamy, Sajani 127:05-127:19 R Swamy, Sajani 129:15-129:21 R Swamy, Sajani 129:15-129:21 R Swamy, Sajani 129:23-130:02 R Swamy, Sajani Swamy, Sajani 133:07-133:18 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 141:11-142:08 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 145:19-146:09 R Swamy, Sajani 145:19-146:09 R Swamy, Sajani 146:11-146:12 R Swamy, Sajani 146:11-146:15 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:17-146:12 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:12-146:13 R		121:14-122:1	BSD, H
Swamy, Sajani 123:18-123:22 R Swamy, Sajani 125:09-125:11 Swamy, Sajani 125:18-126:01 Swamy, Sajani 127:01-127:03 R Swamy, Sajani 127:05-127:19 R Swamy, Sajani 129:15-129:21 R Swamy, Sajani 130:04-130:13 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 133:22-135:11 R Swamy, Sajani 141:11-142:08 R Swamy, Sajani 145:19-146:10 R Swamy, Sajani 145:19-146:19 R Swamy, Sajani 146:11-146:12 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:21-146:13 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:21-146:12 R		121:14-122:1	BSD, H
Swamy, Sajani 125:09-125:11 Swamy, Sajani 125:18-126:01 Swamy, Sajani 127:01-127:03 Swamy, Sajani 127:05-127:19 Swamy, Sajani 129:15-129:21 Swamy, Sajani 129:23-130:02 Swamy, Sajani 130:04-130:13 Swamy, Sajani 133:22-135:11 Swamy, Sajani 133:22-135:11 Swamy, Sajani 142:10-142:10 Swamy, Sajani 145:19-146:17 Swamy, Sajani 145:19-146:19 Swamy, Sajani 146:11-146:12 Swamy, Sajani 146:17-146:19 Swamy, Sajani 146:17-146:19 Swamy, Sajani 146:17-146:19 Swamy, Sajani 146:21-146:12 Swamy, Sajani 146:21-146:12 Swamy, Sajani 146:21-146:12 Swamy, Sajani 146:21-146:13 Swamy, Sajani 146:21-146:23	R, 403, PK, SPEC, O, MIS, F	121:14-122:1	BSD, H
Swamy, Sajani 125:18-126:01 Swamy, Sajani 127:01-127:03 Swamy, Sajani 127:05-127:19 Swamy, Sajani 129:15-129:21 Swamy, Sajani 129:23-130:02 Swamy, Sajani 133:04-130:13 Swamy, Sajani 133:07-133:18 Swamy, Sajani 133:22-135:11 Swamy, Sajani 141:11-142:08 Swamy, Sajani 142:10-142:10 Swamy, Sajani 145:19-146:19 Swamy, Sajani 146:11-146:12 Swamy, Sajani 146:11-146:15 Swamy, Sajani 146:17-146:19 Swamy, Sajani 146:17-146:19 Swamy, Sajani 146:17-146:19 Swamy, Sajani 146:21-146:12 Swamy, Sajani 146:21-146:13 Swamy, Sajani 146:21-146:13 Swamy, Sajani 146:21-146:23 Swamy, Sajani 147:14-147:23			
Swamy, Sajani 127:01-127:03 R Swamy, Sajani 127:05-127:19 R Swamy, Sajani 129:15-129:21 R Swamy, Sajani 129:23-130:02 R Swamy, Sajani 130:04-130:13 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 133:22-135:11 R Swamy, Sajani 141:11-142:08 R Swamy, Sajani 145:09-145:17 R Swamy, Sajani 145:19-146:09 R Swamy, Sajani 146:11-146:12 R Swamy, Sajani 146:11-146:15 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:21-146:23 R Swamy, Sajani 146:21-146:23 R Swamy, Sajani 147:14-147:23 R			
Swamy, Sajani 127:05-127:19 R Swamy, Sajani 129:15-129:21 R Swamy, Sajani 129:23-130:02 R Swamy, Sajani 130:04-130:13 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 133:22-135:11 R Swamy, Sajani 141:11-142:08 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 145:19-146:09 R Swamy, Sajani 146:11-146:12 R Swamy, Sajani 146:14-146:15 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:12-146:19 R Swamy, Sajani 146:12-146:12 R Swamy, Sajani 146:12-146:13 R Swamy, Sajani 146:12-146:12 R Swamy, Sajani 146:12-146:12 R	R, 403, I, F, PK, SPEC, O		
Swamy, Sajani 129:23-130:02 R Swamy, Sajani 130:04-130:13 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 133:22-135:11 R Swamy, Sajani 141:11-142:08 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 145:19-146:19 R Swamy, Sajani 146:11-146:12 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:21-146:12 R Swamy, Sajani 146:21-146:12 R Swamy, Sajani 146:21-146:13 R Swamy, Sajani 146:21-146:23 R Swamy, Sajani 147:14-147:23 R	R, 403, I, NARR, F, PK, SPEC, O		
Swamy, Sajani 130:04-130:13 R Swamy, Sajani 133:07-133:18 R Swamy, Sajani 133:22-135:11 R Swamy, Sajani 141:11-142:08 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 145:09-145:17 R Swamy, Sajani 145:19-146:09 R Swamy, Sajani 146:11-146:12 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:21-146:19 R Swamy, Sajani 146:21-146:12 R Swamy, Sajani 146:21-146:13 R Swamy, Sajani 147:14-147:23 R	R, 403, O, NARR, PK, SPEC		
Swamy, Sajani 133:07-133:18 R Swamy, Sajani 133:22-135:11 R Swamy, Sajani 141:11-142:08 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 145:09-145:17 R Swamy, Sajani 145:19-146:09 R Swamy, Sajani 146:11-146:12 R Swamy, Sajani 146:14-146:15 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:21-146:23 R Swamy, Sajani 147:14-147:23 R	R, 403, O, NARR, PK, SPEC		
Swamy, Sajani 133:22-135:11 R Swamy, Sajani 141:11-142:08 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 145:09-145:17 R Swamy, Sajani 145:19-146:09 R Swamy, Sajani 146:11-146:12 R Swamy, Sajani 146:14-146:15 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:21-146:23 R Swamy, Sajani 147:14-147:23 R	R, 403, O, PK, SPEC		
Swamy, Sajani 141:11-142:08 R Swamy, Sajani 142:10-142:10 R Swamy, Sajani 145:09-145:17 R Swamy, Sajani 145:19-146:09 R Swamy, Sajani 146:11-146:12 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:27-146:19 R Swamy, Sajani 146:21-146:23 R Swamy, Sajani 147:14-147:23 R	R, 403, O, PK, SPEC, V		
Swamy, Sajani 142:10-142:10 R Swamy, Sajani 145:09-145:17 R Swamy, Sajani 145:19-146:09 R Swamy, Sajani 146:11-146:12 R Swamy, Sajani 146:14-146:15 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:21-146:23 R Swamy, Sajani 147:14-147:23 R	R, 403, O, NARR, PK, SPEC, V	405 40 40 405 45 00	
Swamy, Sajani 145:09-145:17 R Swamy, Sajani 145:19-146:09 R Swamy, Sajani 146:11-146:12 R Swamy, Sajani 146:14-146:15 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:21-146:23 R Swamy, Sajani 147:14-147:23 R	R, 403, O, V, PK, SPEC	135:12-13; 135:15-22	BSD, H
Swamy, Sajani 145:19-146:09 R Swamy, Sajani 146:11-146:12 R Swamy, Sajani 146:14-146:15 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:21-146:23 R Swamy, Sajani 147:14-147:23 R		135:12-13; 135:15-22	BSD, H
Swamy, Sajani 146:11-146:12 R Swamy, Sajani 146:14-146:15 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:21-146:23 R Swamy, Sajani 147:14-147:23 R			
Swamy, Sajani 146:14-146:15 R Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:21-146:23 R Swamy, Sajani 147:14-147:23 R			
Swamy, Sajani 146:17-146:19 R Swamy, Sajani 146:21-146:23 R Swamy, Sajani 147:14-147:23 R			-
Swamy, Sajani 146:21-146:23 R. Swamy, Sajani 147:14-147:23 R.			
Swamy, Sajani 147:14-147:23 R			+
	R, 403, F, PK, SPEC, O, V		-
Swamy, Sajani 147:25-148:14 R	R, 403, F, PK, SPEC, O, V	+	
	R, 403, F, PK, SPEC, O, V	151:10-11; 151:13-14; 152:15-19	Н
Swamy, Sajani 154:18-154:21			
Swamy, Sajani 155:03-155:09 R	R, 403, V		
	R, 403, PK, SPEC, F	156:18-23; 156:25-157:6; 157:20-158:10	Н
Swamy, Sajani 155:13-155:16 R		156:18-23; 156:25-157:6; 157:20-158:10	Н
Swamy, Sajani 155:22-156:17 R		156:18-23; 156:25-157:6; 157:20-158:10	Н
Swamy, Sajani 157:08-157:17 R	R, 403, V	156:18-23; 156:25-157:6; 157:20-158:10	Н
Swamy, Sajani 163:04-164:25 R		162:15-17; 162:19-163:2; 165:1-4; 165:6-7	Н
	R, 403, V, MIS, O, SPEC	169:20-170:7; 172:3-7; 172:9-12; 172:14-19; 172:21-173:7; 173:9-11	BSD, H
	R, 403, V, PK, SPEC, O	169:20-170:7; 172:3-7; 172:9-12; 172:14-19; 172:21-173:7; 173:9-11	BSD, H
	R, 403, V, PK, SPEC, O	169:20-170:7; 172:3-7; 172:9-12; 172:14-19; 172:21-173:7; 173:9-11	BSD, H
	R, 403, V, PK, SPEC, O	169:20-170:7; 172:3-7; 172:9-12; 172:14-19; 172:21-173:7; 173:9-11	BSD, H
		169:20-170:7; 172:3-7; 172:9-12; 172:14-19; 172:21-173:7; 173:9-11	BSD, H
Swamy, Sajani 170:21-170:22 R Swamy, Sajani 170:24-171:01 R	R, 403, V, PK, SPEC, O	169:20-170:7; 172:3-7; 172:9-12; 172:14-19; 172:21-173:7; 173:9-11	BSD, H BSD, H

Witness	Natera Designations	Labcorp Objections	Labcorp Counter-Designations	Natera Objections
Swamy, Sajani		R, 403, V, PK, SPEC, O	169:20-170:7; 172:3-7; 172:9-12; 172:14-19; 172:21-173:7; 173:9-11	BSD, H
Swamy, Sajani	_	R, 403, V, PK, SPEC, O	169:20-170:7; 172:3-7; 172:9-12; 172:14-19; 172:21-173:7; 173:9-11	BSD, H
Swamy, Sajani		R, 403, V, PK, SPEC, O	169:20-170:7; 172:3-7; 172:9-12; 172:14-19; 172:21-173:7; 173:9-11	BSD, H
Swamy, Sajani		R, 403, V, PK, SPEC, O	169:20-170:7; 172:3-7; 172:9-12; 172:14-19; 172:21-173:7; 173:9-11	BSD, H
Swamy, Sajani		R, 403, V, PK, SPEC	169:20-170:7; 172:3-7; 172:9-12; 172:14-19; 172:21-173:7; 173:9-11	BSD, H
Swamy, Sajani	174:01-174:01		103.20-170.7, 172.3-7, 172.3-12, 172.14-13, 172.21-173.7, 173.3-11	830,11
	_		107,10 21, 107,22 100,10, 100,2 0, 102,2 4, 102,6 7	BSD, H
Swamy, Sajani	185:13-185:16		187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7	
Swamy, Sajani		R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7	BSD, H
Swamy, Sajani		R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7	BSD, H
Swamy, Sajani		R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7	BSD, H
Swamy, Sajani	187:03-187:18	R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7	BSD, H
Swamy, Sajani	188:12-188:18	R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7	BSD, H
Swamy, Sajani	188:21-188:25	R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7	BSD, H
Swamy, Sajani	189:02-189:11	R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7	BSD, H
Swamy, Sajani		R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7	BSD, H
Swamy, Sajani		R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7	BSD, H
Swamy, Sajani		R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7; 192:19-20, 192:22-23	BSD, H
		R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7; 192:19-20, 192:22-23	BSD, H
Swamy, Sajani	_			
Swamy, Sajani		R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7; 192:19-20, 192:22-23	BSD, H
wamy, Sajani		R, 403, V, PK, SPEC, O, MIS	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7; 192:19-20, 192:22-23	BSD, H
wamy, Sajani		R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7; 192:19-20, 192:22-23	BSD, H
wamy, Sajani		R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7; 192:19-20, 192:22-23	BSD, H
wamy, Sajani	194:12-194:16	R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7; 192:19-20, 192:22-23	BSD, H
wamy, Sajani	194:18-194:18	R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7; 192:19-20, 192:22-23	BSD, H
wamy, Sajani		R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7; 192:19-20, 192:22-23	BSD, H
wamy, Sajani		R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7;192:19-20, 192:22-23	BSD, H
wamy, Sajani		R, 403, V, PK, SPEC, O	187:19-21; 187:23-188:10; 190:2-8; 192:3-4; 192:6-7; 192:19-20, 192:22-23	BSD, H
waniy, Sajani		R, 403, V, PK, SPEC, O, CP	197:5-11	BSD, H
	_			
wamy, Sajani	196:19-197:03		197:5-11	BSD, H
Swamy, Sajani	197:12-197:13		197:5-11	BSD, H
wamy, Sajani	197:15-197:15		197:5-11	BSD, H
wamy, Sajani	197:17-197:20	R, 403, V, SPEC	197:5-11	BSD, H
wamy, Sajani	197:22-198:13	R, 403, V, SPEC, O	197:5-11	BSD, H
wamy, Sajani	199:01-199:08			
wamy, Sajani	200:09-200:11	R. 403. V		
wamy, Sajani	200:17-201:09			
wamy, Sajani	201:11-201:11			
	_			
Swamy, Sajani	_	R, 403, V, CP, O, NARR, MIS		
Swamy, Sajani		R, 403, V, CP, O, NARR, MIS		
Swamy, Sajani		R, 403, V, CP, O, NARR, MIS		
Swamy, Sajani	_	R, 403, V, CP, O, NARR, MIS		
Swamy, Sajani	202:08-202:11	R, 403, V, CP, O, NARR, MIS		
Swamy, Sajani	202:13-202:13	R, 403, V, CP, O, NARR, MIS		
Swamy, Sajani	202:15-202:23	R, 403, V, CP, O, NARR, MIS		
Swamy, Sajani	205:14-205:21	R, 403, V, SPEC		
wamy, Sajani	207:03-208:06	R, 403, V, SPEC, PK		
wamy, Sajani	_	R, 403, V, SPEC, PK, O		
wamy, Sajani	_	R, 403, V, SPEC, PK, O		
wamy, Sajani	_	I, R, 403, H, SPEC, PK, V		
wamy, Sajani		R, 403, H, SPEC, PK, V	+	-
wamy, Sajani	212:21-212:23	· · ·		
wamy, Sajani	212:25-212:25			
wamy, Sajani		R, 403, V, SPEC, O		
wamy, Sajani	_	R, 403, V, SPEC, O		
wamy, Sajani	214:16-214:18	R, 403, V, PK, SPEC, O		
wamy, Sajani		R, 403, V, PK, SPEC, O		
wamy, Sajani		R, 403, V, PK, SPEC, O	215:10-12; 215:14-16	BSD, H
wamy, Sajani		R, 403, V, PK, SPEC, O	215:10-12; 215:14-16	BSD, H
wamy, Sajani		R, 403, V, PK, SPEC, O	215:10-12; 215:14-16	BSD, H
	_		·	
wamy, Sajani		R, 403, V, PK, SPEC, O	215:10-12; 215:14-16	H
wamy, Sajani	_	R, 403, V, SPEC, O	215:10-12; 215:14-16	Н
wamy, Sajani	_	R, 403, V, SPEC, O	215:10-12; 215:14-16	Н
wamy, Sajani		R, 403, V, SPEC, PK	215:10-12; 215:14-16	Н
wamy, Sajani		R, 403, V, SPEC, PK	215:10-12; 215:14-16	Н
wamy, Sajani	224:24-224:25	R, 403, V, SPEC, F		
wamy, Sajani	225:08-225:11	R, 403, V, SPEC, PK		
wamy, Sajani	_	R, 403, V, SPEC, PK		
wamy, Sajani	_	R, 403, V, SPEC, PK		<u> </u>
wamy, Sajani		R, 403, V, SPEC, PK		<u> </u>
		R, 403, V, SPEC, PK		-
wamy, Sajani	_			
wamy, Sajani	_	R, 403, V, SPEC, PK		
wamy, Sajani	_	R, 403, V, SPEC, PK		
wamy, Sajani	227:02-227:06			
wamy, Sajani	228:10-228:14	R, 403, V, SPEC, PK, MIS, O	228:21-25	BSD, H
wamy, Sajani		R, 403, V, SPEC, PK, MIS, O	228:21-25	BSD, H
wamy, Sajani		R, 403, V, SPEC, PK, MIS, O	228:21-25	BSD, H
wamy, Sajani		R, 403, V, MIS, O	228:21-25	BSD, H
wamy, Sajani		R, 403, V, MIS, O	232:6-11; 232:13-18	BSD, H
wamy, Sajani		R, 403, SPEC, PK, V	232:6-11; 232:13-18	BSD, H
wamy, Sajani		R, 403, SPEC, PK, V	232:6-11; 232:13-18	BSD, H
	1 222.12 222.14	R, 403, SPEC, PK, V	232:6-11; 232:13-18	BSD, H
wamy, Sajani		R, 403, SPEC, PK, V	232:6-11; 232:13-18	BSD, H

Witness	Natera	Labcorp Objections	Labcorp Counter-Designations	Natera Objections
	Designations			
Velenich, Andrea	006:24-008:18			
Velenich, Andrea Velenich, Andrea	018:03-018:10 021:01-022:04	V 403		
Velenich, Andrea	023:05-023:08		24:12-17, 29:21-30:1	BSD, H
Velenich, Andrea	023:10-023:12		24:12-17, 29:21-30:1	BSD, H
Velenich, Andrea	024:07-024:11		24:12-17, 29:21-30:1	BSD, H
Velenich, Andrea	024:22-025:04	CP, PK, V, R, 403	24:12-17, 29:21-30:1	BSD, H
Velenich, Andrea		CP, PK, V, R, 403	24:12-17, 29:21-30:1	BSD, H
Velenich, Andrea	025:15-025:21	V 2 10 100	24:12-17, 29:21-30:1	BSD, H
Velenich, Andrea Velenich, Andrea	027:10-027:16 028:20-028:21		24:12-17, 29:21-30:1	DCD H
Velenich, Andrea	028:23-029:07		24:12-17, 29:21-30:1	BSD, H BSD, H
Velenich, Andrea	029:09-029:10		24:12-17, 29:21-30:1	BSD, H
Velenich, Andrea	029:12-029:19	V, R, 403	24:12-17, 29:21-30:1	BSD, H
Velenich, Andrea	030:07-030:13	V, 403		
Velenich, Andrea	030:15-030:16	V, 403		
Velenich, Andrea	030:18-030:24			
Velenich, Andrea	032:06-032:08		24:12-17, 29:21-30:1	BSD, H
Velenich, Andrea	032:10-032:10		24:12-17, 29:21-30:1 24:12-17, 29:21-30:1, 32:23-33:1, 33:4-	BSD, H
Velenich, Andrea	032.12-032.19	F, SPEC, V, R, 403	8	BSD, H
Velenich, Andrea	032:21-032:21	F, SPEC, V, R, 403	24:12-17, 29:21-30:1, 32:23-33:1, 33:4-	BSD, H
Velenich, Andrea	034:05-034:09		8	
Velenich, Andrea		O, SPEC, V, R, 403		
Velenich, Andrea	035:03-035:04	O, SPEC, V, R, 403		
Velenich, Andrea		F, NARR, O, SPEC, V, R, 403		
Velenich, Andrea		F, NARR, O, SPEC, V, R, 403		
Velenich, Andrea		F, NARR, O, SPEC, V, R, 403		
Velenich, Andrea Velenich, Andrea		F, NARR, O, SPEC, V, R, 403 F, NARR, O, SPEC, V, R, 403	+	
Velenich, Andrea		F, I, NARR, O, SPEC, V, R, 403		
Velenich, Andrea		F, NARR, O, SPEC, V, R, 403		
Velenich, Andrea		F, NARR, O, SPEC, V, R, 403		
Velenich, Andrea	036:15-036:20	F, NARR, O, SPEC, V, R, 403		
Velenich, Andrea		F, NARR, O, SPEC, V, R, 403		
Velenich, Andrea	037:03-037:12			
Velenich, Andrea		AA, ARG, CP, F, MIS, NARR, O, OB, R, SPEC, 403, V		
Velenich, Andrea Velenich, Andrea	040:03-040:03	AA, ARG, CP, F, MIS, NARR, O, OB, R, SPEC, 403, V		
Velenich, Andrea		SPEC, V, R, 403		
Velenich, Andrea		SPEC, V, R, 403		
Velenich, Andrea		MIS, NARR, R, 403	43:3-7, 43:9-17	Н
Velenich, Andrea	042:23-043:01	MIS, NARR, R, 403	43:3-7, 43:9-17	Н
Velenich, Andrea	047:01-047:05	V	47:6-8, 47:10-15; 104:4-5, 104:7-10	BSD, H
Velenich, Andrea	047:24-048:02			
Velenich, Andrea	048:17-049:04	V P 403	+	
Velenich, Andrea	049:06-049:09		+	
Velenich, Andrea Velenich, Andrea	049:11-049:13 049:15-050:05	O, SPEC, V, R, 403	+	
Velenich, Andrea		O, SPEC, V, R, 403		
Velenich, Andrea	061:06-061:15			
Velenich, Andrea	065:12-065:12	I, R, 403		
Velenich, Andrea	065:18-065:08			
Velenich, Andrea		OB, F, CP, V, R, 403	47.0 0 47.40 45 404.4 5 404.7 40	DCD 11
Velenich, Andrea	069:20-070:12	ν, κ, 4U3	47:6-8, 47:10-15; 104:4-5, 104:7-10	BSD, H
Velenich, Andrea Velenich, Andrea	073:08-073:13	PK, SPEC, V, R, 403	+	
Velenich, Andrea		PK, SPEC, V, R, 403		
Velenich, Andrea	077:01-077:04			
Velenich, Andrea	077:13-077:19			
Velenich, Andrea	077:21-078:05			
Velenich, Andrea	078:07-079:13		1	
Velenich, Andrea		SPEC, V, R, 403	+	
	U8U:U9-U8U:15	SPEC, V, R, 403	+	
Velenich, Andrea	080·17-020·22	ISPEC V R 403		
Velenich, Andrea Velenich, Andrea Velenich, Andrea	080:17-080:22 080:24-080:24	SPEC, V, R, 403 SPEC, V, R, 403	+	

Witness	Natera	Labcorp Objections	Labcorp Counter-Designations	Natera Objections
	Designations			
elenich, Andrea	087:19-087:19	PK, V, R, 403	24:12-17, 29:21-30:1	BSD, H
elenich, Andrea	090:10-090:12			
/elenich, Andrea	090:21-091:03			
elenich, Andrea	092:13-092:17			
/elenich, Andrea	094:13-094:15	LC, MIS, PK, R, SPEC, 403, V	139:24-140:3, 140:6-9	BSD, H
elenich, Andrea	094:17-095:06	LC, MIS, PK, R, SPEC, 403, V	139:24-140:3, 140:6-9	BSD, H
/elenich, Andrea	095:08-095:15	LC, MIS, PK, R, SPEC, 403, V	139:24-140:3, 140:6-9	BSD, H
elenich, Andrea	096:01-096:03			
elenich, Andrea	096:12-097:01			
elenich, Andrea	097:03-097:04			
elenich, Andrea	097:12-097:17			
/elenich, Andrea	099:12-099:17			
/elenich, Andrea	100:01-100:17	SPEC, V, R, 403		
/elenich, Andrea	100:20-101:04	O, SPEC, V, R, 403	47:6-8, 47:10-15	BSD, H
/elenich, Andrea	101:07-101:16	O, SPEC, V, R, 403	47:6-8, 47:10-15	BSD, H
/elenich, Andrea	101:18-101:20	SPEC, V, R, 403		
/elenich, Andrea	102:01-102:05	SPEC, V, R, 403		
/elenich, Andrea	102:07-102:22		102:23-103:2, 103:4-7, 104:4-5, 104:7-	BSD, H
			10	
/elenich, Andrea	112:24-113:04	O, PK, 403		
/elenich, Andrea	113:17-113:18	O, SPEC, V, R, 403		
/elenich, Andrea	113:20-113:23	O, SPEC, V, R, 403		
/elenich, Andrea	114:01-114:06	O, SPEC, V, R, 403		
/elenich, Andrea		PK, SPEC, V, R, 403		
/elenich, Andrea	114:20-116:15	ARG, LC, R, 403		
/elenich, Andrea	116:17-117:08	ARG, LC, R, 403		
/elenich, Andrea	119:01-119:04			
/elenich, Andrea	121:04-121:09	LC, PK, SPEC, V, R, 403		
/elenich, Andrea	121:11-122:17	LC, PK, SPEC, V, R, 403		
/elenich, Andrea	123:05-123:10	LC, PK, SPEC, V, R, 403		
/elenich, Andrea	123:12-123:16	LC, PK, SPEC, V, R, 403		
/elenich, Andrea	125:10-125:20	LC, PK, SPEC, V, R, 403		
elenich, Andrea	125:22-125:24	LC, PK, SPEC, V, R, 403		
/elenich, Andrea		LC, PK, SPEC, V, R, 403		
/elenich, Andrea		LC, PK, SPEC, V, R, 403		
/elenich, Andrea	127:01-127:02			
elenich, Andrea	127:09-127:20			
/elenich, Andrea	127:24-127:24	I, R, 403		
. ,		1 ' '		

EXHIBIT 10 -REDACTED IN ITS ENTIRETY

EXHIBIT 11 - REDACTED IN ITS ENTIRETY

EXHIBIT 12

Case 1:21-cv-01635-GBW

Document 302-1 Filed 08/27/25 Laboratory Corp. of America Holdings v. Natera, Inc. #C.A. No 22/365+

Page 274 of 739 PageID

C.A. No. 21-1635 Joint Trial Exhibit List

JTX Exhibit					
No.		Description	Bates Beg No.	Bates End No.	Witness
1	3/31/2020	U.S. Patent No. 10,604,799 (Porreca et al.)	Invitae0000007800	Invitae0000007822	
2	4/11/2014	U.S. Patent No. 10,604,799 File History (Application No. 14/250,891	Invitae000000001	Invitae0000002508	
3	10/19/2021	U.S. Patent No. 11,149,308 (Porreca et al.)	Invitae0000007823	Invitae0000007850	
4	5/17/2021	U.S. Patent No. 11,149,308 File History (Application No. 17/322,610	Invitae0000002509	Invitae0000002794	
5	10/26/2021	U.S. Patent No. 11,155,863 (Porreca et al.)	Invitae0000007851	Invitae0000007877	
6	5/17/2021	U.S. Patent No. 11,155,863 File History (Application No. 17/322,587	Invitae0000002795	Invitae0000003098	

EXHIBIT 13

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY C AMERICA HOLD	CORPORATION OF INGS,)	
	Plaintiff,)	C.A. No. 21-669 (GBW)
v.)	
NATERA, INC.)	
	Defendant.)	
LABORATORY C AMERICA HOLD	CORPORATION OF VINGS,))	
	Plaintiff,)	C.A. No. 21-1635 (GBW)
v.)	
NATERA, INC.)	
	Defendant.	,	

EXHIBIT 13: PLAINTIFF'S STATEMENT OF INTENDED PROOFS

Pursuant to Delaware Local Rule 16.3(c)(8), Plaintiff Laboratory Corporation of America Holdings ("Labcorp") hereby submits the following brief statement of what Labcorp intends to prove in support of its claims at trial, including the details of the damages claimed or of other relief sought. This statement is not intended to be exhaustive, and Labcorp reserve the right to prove any matters identified in the pleadings, fact and expert discovery, and any of the accompanying statements of facts and legal issues to be litigated at trial. With respect to proof to be presented by expert testimony, Labcorp incorporates by reference the reports and depositions of Labcorp's expert witnesses addressing the issues identified below.

Labcorp further reserve the right to amend and/or supplement this statement to the extent necessary to respond to issues raised by Defendant Natera, Inc. ("Natera") and to rebut any alleged proof(s) offered by Natera before and during trial, in response to rulings by the Court, or for any other reason.

I. INFRINGEMENT OF THE PATENTS-IN-SUIT

A. Infringement of the '799 Patent

1. Labcorp will prove by a preponderance of the evidence that Natera directly infringes, literally and/or under the doctrine of equivalents, the '799 Asserted Claims under 35 U.S.C. § 271(a) by performing the claimed process of the '799 Asserted Claims using the Signatera test.

B. Infringement of the '308 Patent

2. Labcorp will prove by a preponderance of the evidence that Natera directly infringes, literally and/or under the doctrine of equivalents, the '308 Asserted Claims under 35 U.S.C. § 271(a) by performing the claimed process of the '308 Asserted Claims using the Signatera test.

C. Infringement of the '863 Patent

3. Labcorp will prove by a preponderance of the evidence that Natera directly infringes, literally and/or under the doctrine of equivalents, the '863 Asserted Claims under 35 U.S.C. § 271(a) by performing the claimed process of the '863 Asserted Claims using the Signatera test.

II. REMEDIES

- 4. Labcorp will prove by a preponderance of the evidence that it is entitled to lost profits related to Natera's use of the Signatera test.
- 5. Labcorp will prove by a preponderance of the evidence that it is entitled to reasonable royalties related to Natera's use of the Signatera test.
- 6. Labcorp will prove by a preponderance of the evidence that it is entitled to attorneys' fees and costs pursuant to 35 U.S.C. § 285 as a result of Natera's infringement of one or more of the Asserted Claims of the '799 Patent, the '308 Patent, and/or the '863 Patent.
- 7. Natera bears the burden of proving that they are entitled to any remedies, including that this is an exceptional case and/or attorneys' fees and costs pursuant to 35 U.S.C. § 285 in the event one or more of the Asserted Claims of the Asserted Patents are found not infringed and invalid. Labcorp, to the extent necessary, will introduce evidence to rebut Natera's assertion that it is entitled to any remedies, including that this is an exceptional case and/or attorneys' fees and costs pursuant to 35 U.S.C. § 285.
- 8. Labcorp will prove by a preponderance of the evidence that it is entitled to a permanent injunction enjoining Natera, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from using Natera's Signatera test prior to the expiration of the Asserted Patents, pursuant to 35 U.S.C. § 283.

III. VALIDITY

- 9. Natera bears the burden of establishing by clear and convincing evidence that the Asserted Claims of the Asserted Patents are invalid under 35 U.S.C. § 101. Labcorp, to the extent necessary, will introduce evidence to rebut Natera's assertion that the Asserted Claims of the Asserted Patents are invalid under 35 U.S.C. § 101.
- 10. Natera bears the burden of establishing by clear and convincing evidence that the Asserted Claims of the Asserted Patents are invalid as anticipated under 35 U.S.C. § 102. Labcorp, to the extent necessary, will introduce evidence to rebut Natera's assertion that the Asserted Claims of the Asserted Patents are anticipated under 35 U.S.C. § 102.
- 11. Natera bears the burden of establishing by clear and convincing evidence that the Asserted Claims of the Asserted Patents are invalid as obvious under 35 U.S.C. § 103. Labcorp, to the extent necessary, will introduce evidence to rebut Natera's assertion that the Asserted Claims of the Asserted Patents are obvious under 35 U.S.C. § 103, such as evidence of objective indicia of non-obviousness.
- 12. Natera bears the burden of establishing by clear and convincing evidence that the Asserted Claims of the Asserted Patents are invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112. Labcorp, to the extent necessary, will introduce evidence to rebut Defendants' assertion that the Asserted Claims of the Asserted Patents are invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112.
- 13. Natera bears the burden of establishing by clear and convincing evidence that the Asserted Claims of the Asserted Patents are invalid for failure to satisfy the enablement requirement of 35 U.S.C. § 112. Labcorp, to the extent necessary, will introduce evidence to rebut

Natera's assertion that the Asserted Claims of the Asserted Patents are invalid for failure to satisfy the enablement requirement of 35 U.S.C. § 112.

Asserted Claims of the Asserted Patents are invalid for failure to satisfy the definiteness requirement of 35 U.S.C. § 112. Labcorp objects to Defendants' inclusion of this invalidity ground as an intended proof for the jury trial. Labcorp, to the extent necessary, will introduce evidence to rebut Natera's assertion that the Asserted Claims of the Asserted Patents are invalid for failure to satisfy the definiteness requirement of 35 U.S.C. § 112.

EXHIBIT 14

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

C.A. No. 21-cv-669-GBW

C.A. No. 21-cv-1635-GBW

EXHIBIT 14: DEFENDANT'S BRIEF STATEMENT OF INTENDED PROOFS

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Exhibit 14

Joshua A. Rosefelt GROOMBRIDGE, WU, BAUGHMAN & STONE LLP 801 17th Street, NW, Suite 1050 Washington, DC 20006 (202) 505-5830 Natera respectfully submits the following statement of intended proofs. Further details regarding these intended proofs have been explained at length in Natera's pleadings and discovery responses, including in its contentions, interrogatory responses, expert reports, by experts at depositions, and by fact witnesses at depositions. Natera reserves the right to revise, modify, supplement, or change its statement of intended proofs in response to subsequent Court rulings and/or to rebut Labcorp's identification of issues of law and fact to be litigated and any alleged intended proof(s) or any new issues Labcorp may raise, or for other good cause. The following Statement of Intended Proofs is not exhaustive and Natera reserves the right to prove any matters identified in the pleadings and discovery responses, including in its contentions, expert reports, by experts at depositions, and by fact witnesses at depositions.

Natera will rebut any assertions by Labcorp regarding the intended proofs that Labcorp has set forth in Exhibit 13. Further details regarding Natera's intended proofs are available in Natera's Answer and Counterclaims (D.I. 31); and Natera's discovery responses, including its contentions, interrogatories (including any supplemental responses), and expert reports, as well as statements of experts at depositions, as well as the intended proofs set forth in the parties' Statement of Uncontested Facts, Natera's Statement of Contested Issues of Fact That Remain to Be Litigated, and Natera's Statement of Contested Issues of Law That Remain to Be Litigated, submitted herewith.

I. THE ASSERTED PATENTS ARE INVALID

- 1. Natera will prove that it is entitled to a judgment that the Asserted Claims of the Asserted Patents are invalid.
- 2. Natera will prove by clear and convincing evidence that the Asserted Claims of the Asserted Patents are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112.

A. Non-Patentable Subject Matter¹

3. Natera will prove by clear and convincing evidence that the Asserted Claims of the Asserted Patents claim non-patentable subject matter under 35 U.S.C. § 101.

B. Anticipation

4. Natera will prove by clear and convincing evidence that the Asserted Claims of the Asserted Patents are invalid as anticipated under 35 U.S.C. § 102.

C. Obviousness

- 5. Natera will prove by clear and convincing evidence that the Asserted Claims of the Asserted Patents are invalid as obvious under 35 U.S.C. § 103.
- 6. To the extent Labcorp attempts to rely upon any secondary considerations of nonobviousness, and to the extent Labcorp comes forward with evidence of any such secondary considerations and evidence purporting to show nexus, Natera will introduce evidence to rebut Labcorp's assertions of both nexus and any such secondary considerations.

D. Enablement

7. Natera will prove by clear and convincing evidence that the Asserted Claims of the Asserted Patents are invalid for failure to satisfy the enablement requirement of 35 U.S.C. § 112.

E. Written Description

8. Natera will prove by clear and convincing evidence that the Asserted Claims of the Asserted Patents are invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112.

¹ Natera refers the Court to its Statement of Additional Matters concerning the presentation and adjudication of the subject-matter-eligibility challenge to the Asserted Claims.

F. Indefiniteness

9. Natera will prove by clear and convincing evidence that the Asserted Claims of the Asserted Patents are invalid as indefinite under 35 U.S.C. § 112.

G. Priority Date

10. Natera will rebut any evidence presented by Labcorp to show that the Asserted Claims of the '799, '308, and '863 Patents are entitled to priority dates earlier than their respective application filing dates.

II. NATERA DOES NOT INFRINGE THE ASSERTED PATENTS

- 11. Natera will show that Labcorp has failed to meet its burden to prove by a preponderance of the evidence that Natera infringes any of the Asserted Claims of the Asserted Patents by using Signatera in violation of 35 U.S.C. § 271(a). For example, Natera will show that the accused functionality of the Signatera test does not satisfy each limitation of the Asserted Claims of the '799, '308, and '863 Patents, either literally or under the doctrine of equivalents. Natera will also show that the claim vitiation doctrine and the doctrine of ensnarement foreclose Labcorp's theory of equivalence.
- 12. Natera will thus establish that it is entitled to a judgment that Natera does not infringe any of the Asserted Claims of the Asserted Patents.

III. <u>REMEDIES</u>

A. Lost Profits

13. Natera will show that Labcorp has failed to meet its burden to prove by a preponderance of the evidence that, to the extent any of the Asserted Claims of the Asserted Patents are found to be not invalid and infringed, Labcorp is entitled to lost profits damages for the time

period through November 2023.² Natera will also present evidence to rebut Labcorp's claim as to the amount of lost profits damages Labcorp is entitled to.

B. Reasonable Royalty

14. Natera will show that Labcorp has failed to meet its burden to prove by a preponderance of the evidence that, to the extent the Asserted Claims are found to be infringed and not invalid, Labcorp is entitled to the amount of reasonable royalty damages it seeks. Natera will present evidence to rebut Labcorp's asserted reasonable royalty damages amount, royalty base, and royalty rate.

C. Pre-Judgment and Post-Judgment Interest

15. To the extent any of the Asserted Claims of the Asserted Patents are found to be infringed and not invalid, and any damages are awarded, Natera will show that Labcorp has failed to meet its burden to prove by a preponderance of the evidence that it is entitled to pre-judgment and post-judgment interest. To the extent any additional damages are sought by Labcorp post-verdict, Natera will present evidence to rebut Labcorp's asserted damages amount, royalty base, and royalty rate.

D. Permanent Injunction

16. To the extent any of the Asserted Claims of the Asserted Patents are found to be infringed and not invalid, and Labcorp seeks a permanent injunction, Natera will show that Labcorp has failed to meet its burden to prove that Labcorp is entitled to a permanent injunction enjoining Natera's use of the accused functionality in Signatera until the expiration of the Asserted Patents.

² Labcorp has confirmed that it does not seek lost profits for the period after November 2023.

E. Exceptional Case

- 17. Natera will show that Labcorp has failed to meet its burden to prove that the case is exceptional under 35 U.S.C. § 285.
- 18. To the extent one or more of the Asserted Claims of the Asserted Patents is found to be not infringed and/or invalid, Natera will prove that this is an exceptional case under 35 U.S.C. § 285.

F. Attorneys' Fees, Costs, and Litigation Expenses

- 19. To the extent one or more of the Asserted Claims of the Asserted Patents is found to be not infringed and/or invalid, Natera will prove that Natera is entitled to attorneys' fees, costs, and litigation expenses under 35 U.S.C. § 285 and will prove the amount.
- 20. Natera will prove that it is entitled to any other relief as this Court deems just and proper.

EXHIBIT 15

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION OF AMERICA HOLDINGS,)
Plaintiff,) C.A. No. 21-669 (GBW)
v.) HIGHLY CONFIDENTIAL –) ATTORNEY'S EYES ONLY
NATERA, INC.)
Defendant.)
LABORATORY CORPORATION OF AMERICA HOLDINGS,)))
Plaintiff,) C.A. No. 21-1635 (GBW)
V.	
NATERA, INC.)
Defendant.)

EXHIBIT 15: PLAINTIFF'S STATEMENT OF ADDITIONAL MATTERS

Pursuant to Delaware Local Rule 16.3(c)(13), Plaintiff Laboratory Corporation of America Holdings ("Plaintiff" or "Labcorp") hereby submit the following additional matters:

1. Natera's 101 Challenges

As Plaintiff describes in its first motion *in limine*, Plaintiff seeks the Court's ruling that Judge Stark's Order on November 30, 2021 (D.I. 28¹ at 5), bars Natera from re-litigating the patent eligibility of the '799 Patent pursuant to 35 U.S.C. § 101 because of the law of the case. *See Kove IO, Inc. v. Amazon Web Services, Inc.*, 2024 WL 450028, *16–*18 (N.D. III. 2024) (ruling that the law of the case applied to the court's finding on a motion to dismiss and dismissing an accused infringer's § 101 challenge). Judge Stark's eligibility ruling should apply with equal force to the '863 and '308 Patents, which, as is evident from the claim language, have claims with *narrower* scope than those of the '799 Patent.

2. Invitae's Bankruptcy

Natera should be precluded from introducing evidence, testimony, or argument related to Invitae's bankruptcy proceedings, including Invitae's financial health leading up to its bankruptcy, the circumstances that may have led to Invitae's bankruptcy, and the other suit between Natera and Invitae (Case No. 20-125-GBW). As explained in Plaintiff's second and third motions *in limine*, evidence of the prior litigation between Invitae and Natera and Invitae's financial health are highly prejudicial to Plaintiff and may mislead the jury when deciding upon issues of infringement invalidity in this case.

¹ Citations are to Case No. 21-669-GBW.

3. Asserted Patents' Critical Dates

Natera should be precluded from introducing evidence, testimony, or argument that contest the asserted patents' priority dates or when the invention was conceived and reduced to practice. None of Natera's experts have proffered opinions on these issues. Yet, Natera includes them in its Statement of Contested Issues of Fact and Statement of Contested Issues of Law. Plaintiff seeks the Court's clarification that that Natera is precluded from eliciting evidence on these issues.

4. Natera's Patents That Signatera Embody

Natera should be precluded from introducing evidence, testimony, or argument that Natera's accused product Signatera does not infringe the asserted patents because it embodies or practices other Natera patents. Whether other Natera patents cover Signatera is irrelevant in this case to the issue of infringement of the asserted patents. *See Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1581 (Fed. Cir. 1984) ("Patentable difference does not of itself tend to negative infringement. It may just as well be based upon infringement, plus improvement; and improvement may lie in addition, simplification, or variance."); *Temco Elec. Motor Co. v. Apco Mfg. Co.*, 275 U.S. 319, 328 (1928) ("It is well established that an improver cannot appropriate the basic patent of another, and that the improver without a license is an infringer, and may be sued as such."). Discussion of Natera patents is more like to confuse than help the jury.

5. The Court's Claim Construction Order

Natera should be precluded from introducing evidence, testimony, or argument relating to the Court's Claim Construction Order (D.I. 85) other than the Court's actual adopted constructions. Any attempt by Natera to introduce additional language outside of the claim construction order such as the Court's reasoning, the parties' arguments, and Plaintiff's motion for reconsideration

are more likely to confuse than help the jury and should therefore be excluded under Rule 403. Claim construction "falls 'exclusively within the province of the court" and the claim construction order "dictate[s] how *the court* will instruct the jury regarding a claim's scope." *Astellas Pharma Inc. v. Zydus, Inc.*, No. 1:20CV1589, 2025 WL 1650497, at *3 (D. Del. June 10, 2025) (quoting *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1359 (Fed. Cir. 2008)) (emphasis added). Presenting lengthy portions of the Court's Claim Construction Memorandum Opinion (D.I. 85) to the jury is inappropriate and would create a sideshow wherein *the parties* seek to debate before the jury the meaning of various aspects of this opinion. Each side attempting to influence the jury regarding the scope and interpretation of the claims impedes on the Court's exclusive authority over claim construction and will confuse the jury as to the actual claim scope.

Presenting the Court's actual adopted constructions from the Court's Claim Construction Order properly instructs the jury regarding the scope of the claims. See Sunny Fresh Foods, Inc. v. Michael Foods, Inc., 130 F. App'x 459, 464-65 (Fed. Cir. 2005) ("Lastly, Michael Foods argues that the district court erred by providing the jury with 'a short synopsis' of the claim construction order. The district court, in fact, provided a copy of the district court's claim constructions with the jury instructions. Stated more accurately, Michael Foods's complaint is that the district court provided the jury with merely the disputed claims and their respective definitions but excluded the dicta in the district court's claim construction order setting forth the reasoning accompanying the actual definitions. This court finds no error in this practice. The district court clearly instructed the jury on the meaning of the disputed claim terms. The law requires no more."); MercExchange, LLC v. eBay, Inc., 401 F.3d 1323, 1329 (Fed. Cir. 2005), vacated on other grounds and remanded, 547 U.S. 388 (2006) ("We also agree with the district court that it was not necessary for the court

to include excerpts from its Markman order in the jury instructions. A district court's Markman order is an explanation to the parties of the reasoning behind its claim construction. The court's analysis need not be part of the jury instructions."); Hillman Group, Inc. v. KevMe, LLC, 2021 WL 1248180, *4 (E.D. Tex. 2021) (refusing to permit either party presenting to the jury any claim construction materials, including tutorials presented to the court during the claim construction hearing—"Neither party is permitted to present claim construction materials (including tutorials) in a jury trial. The parties are expected to comply with the Court's previous order as stated in the July 2, 2020 claim construction opinion: 'The parties are ordered that they may not refer, directly or indirectly, to each other's claim construction positions in the presence of the jury. Likewise, the parties are ordered to refrain from mentioning any portion of this opinion, other than the actual definitions adopted by the Court, in the presence of the jury. Any reference to claim construction proceedings is limited to informing the jury of the definitions adopted by the Court.""); Boston Scientific Corp. v. Cook Medical LLC, No. 1:17-cv-03448-JRS-MJD, 2023 WL 3604030, at *3 (S.D. Ind. May 22, 2023) ("For the following reasons, the Court precludes Plaintiffs from presenting 'dicta' from the claim construction order to the jury . . . and the jury should only be presented with the final construction adopted by the Court'); Schwendimann v. Arkwright Advanced Coating, Inc., No. CV 11-820 (JRT/HB). 2018 WL 1064556, at *6 (D. Minn. Feb. 26, 2018) ("The Court's Claim Construction Order is a lengthy order that contains a significant amount of discussion and analysis. Both parties sought to include dicta from the Claim Construction Order in the jury instructions. . . . Consistent with the Court's practice, the Court refused to include the additional discussion that accompanied the construction of 'mix' and 'melt."").

6. Case Narrowing

There is an outstanding issue as to case narrowing. Labcorp proposed narrowing the claims it would assert at trial to ten total claims with no more than four claims per patent in exchange for

Natera narrowing its invalidity grounds to no more than two prior art grounds per patent (each of which is specifically tethered to properly disclosed prior art) and no more than two § 112 defenses per patent. Labcorp based its proposal for the narrowing of the prior art grounds on the case narrowing order from the parties' prior litigation. *See Natera, Inc. v. ArcherDX, Inc.*, C.A. No. 20-125-GBW, D.I. 589, Oral Order (5/5/2023) (Defendants shall specifically identify, as it relates to each patent, up to two prior art defenses (i.e., § 102, § 103) and tether each defense to properly disclosed prior art references. By way of example only, for the '220 patent, Defendants may choose to assert (1) § 102 in view of Iafrate, and (2) § 102 in view of Faham, but as a result, Defendants could not then assert either § 103 in view of Faham OR § 103 in view of Faham and Broude").

Natera has thus far not agreed to Labcorp's proposal. Natera's most recent counterproposal was that Natera would narrow to three prior art grounds per patent, but that Natera would count both an anticipation and a single-reference obviousness defense based on the same prior art as one ground, not two. Natera also did not agree to three § 112 defenses per patent. Natera's counterproposal, is unreasonable and not in line with this Court's order in the prior litigation between the parties. Most troubling, Natera's experts rely upon 11 different primary prior art references in their reports, and for each of them Natera advances both anticipation and single-reference obviousness. Thus, Natera's proposal, if adopted, would allow it to effectively *double* the number of invalidity grounds. Natera's refusal to the number of § 112 defenses is similarly unreasonable.

EXHIBIT 16

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

C.A. No. 21-cv-669-GBW

C.A. No. 21-cv-1635-GBW

EXHIBIT 16: DEFENDANT'S BRIEF STATEMENT OF <u>ADDITIONAL MATTERS</u>

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Joshua A. Rosefelt GROOMBRIDGE, WU, BAUGHMAN & STONE LLP 801 17th Street, NW, Suite 1050 Washington, DC 20006 (202) 505-5830 Natera respectfully submits the following statement of additional matters. Based on the current state of this action and the Court's rulings to date, Natera presents the following list of issues that it would like to address at the Pretrial Conference scheduled for September 3, 2025. Natera reserves the right to revise, modify, supplement, or amend this list based on issues raised by Labcorp, orders by the Court, negotiations between the parties, and/or for other good cause.

I. SUMMARY JUDGMENT AND *DAUBERT* MOTIONS

On September 29, 2023, Natera filed its Motions for Summary Judgment and to Preclude Certain Expert Testimony and accompanying materials. D.I. 214–227. On October 20, 2023, Labcorp (then, Invitae) filed its opposition and accompanying materials. D.I. 246–250. On November 13, 2023, Natera field its reply and accompanying materials. D.I. 260, 262, 264, 266, 267.

On September 29, 2023, Labcorp (then Invitae) filed its Motions for Summary Judgment and *Daubert* Motion to Exclude Expert Testimony and accompanying materials. D.I. 210. On October 20, 2023, Natera filed its opposition and accompanying materials. D.I. 242–245. On November 13, 2023, Labcorp filed its reply and accompanying materials. D.I. 261, 263, 265.

The Court has not yet ruled on Natera's summary judgment motions, and has not yet ruled on all of the parties' *Daubert* motions. Resolution of Natera's summary judgment motions may entirely resolve the issues for trial, as some of Natera's motions are entirely case dispositive: Natera has moved for summary judgment that Natera does not infringe the Asserted Patents literally or under the doctrine of equivalents, D.I. 218–223, and that certain of the Asserted Claims are invalid as anticipated under 35 U.S.C. §§ 102(a) and 102(g). D.I. 224–226. At a minimum,

¹ Docket cites are to C.A. No. 21-669 unless otherwise specified.

resolution of the motions may streamline the jury trial by resolving certain issues and disposing of a number of evidentiary disputes.

II. THE COURT'S CONSTRUCTION OF "SEQUENCE READS"

The Court construed the term "sequence reads" as "raw reads as generated by the sequencing instrument." D.I. 84 at 5. Twice, the Court has explained that raw reads, as construed, "do not include any pre-processing or pre-alignment steps performed between sequencing and the claimed manipulation of those reads." D.I. 84 at 5–6; see also D.I. 184 at 3. Labcorp has made clear that it opposes the jury ever being told, in any way, that raw reads do not include pre-processing or pre-alignment steps. Labcorp wants the ability to argue that pre-aligned reads, or pre-processed reads, or pre-aligned and pre-processed reads, are somehow "raw," despite the Court twice having held otherwise. Labcorp's asserted basis is that the language excluding pre-alignment and pre-processing is in the Court's opinion, not in its construction. To that end, Labcorp has refused to include in the Cover Pleading and the Statement of Undisputed Facts that the Court's construction means that the claimed "sequence reads" are unaligned and unprocessed.

Labcorp is incorrect. The Court made clear—both in its *Markman* decision and its decision denying Labcorp's motion for reconsideration or clarification of its construction of "sequence reads"—that its construction of "raw reads" excludes any pre-aligned and pre-processed reads: "The Court's Opinion about 'sequence reads' is unambiguous... the Court wrote, Defendant Natera, Inc. ('Natera') 'asserts that the claim term "sequence reads" do not include any pre-processing or pre-alignment steps performed between sequencing and the claimed manipulation of those reads. The Court agrees with Natera...." D.I. 184 at 3. The Court further explained "[t]hat 'pre-aligned' reads are not 'raw reads' and thus are excluded from the Court's construction of 'sequence reads' is clear from the opinion itself." *Id*.

Natera respectfully requests that the Court address this issue at the Pretrial Conference, and hold that the jury should be informed that the Court has construed "sequence reads" to mean "raw reads as generated by the sequencing instrument," which "do not include any pre-processing or pre-alignment steps performed between sequencing and the claimed manipulation of those reads." D.I. 184 at 3. Natera is not wedded to any particular form by which the jury is so informed; whether that definition comes in as a jury instruction, an agreed-upon statement to be read to the jury, or through the Court's opinion itself is not itself material. What matters is that the jury learn what the Court has said the construction means, and that Labcorp not be allowed to suggest, argue, or imply otherwise. Misleading the jury should not be Labcorp's next gambit to seek reconsideration of the Court's claim construction. Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1321 (Fed. Cir. 2009) ("No party may contradict the court's construction to a jury."); Kangaroo Media, Inc. v. YinzCam, Inc., C.A. No. 12-0382, 2014 WL 3378692, at *2 (W.D. Pa. July 9, 2014) ("No party will be permitted to argue its rejected claim construction position to the jury."); EMC Corp. v. Pure Storage, Inc., C.A. No. 13-1985, 2016 WL 775742, at *4 (D. Del. Feb. 25, 2016) ("[Party] is precluded from arguing a meaning to the jury through its expert that it already argued to the Court in the context of claim construction, as that truly would be 'arguing claim construction to the jury."); Mobile Telecommunications Techs., LLC v. Zte (USA) Inc., C.A. No. 13-946, 2016 WL 8260584, at *3 (E.D. Tex. July 22, 2016) ("The parties SHALL NOT introduce any references, evidence, testimony (including expert testimony), or argument that is inconsistent with the Court's Claim Construction Memorandum and Order"); LifeNet Health v. LifeCell Corp., C.A. No. 13-486, 2014 WL 5529679, at *6-7 (E.D. Va. Oct. 31, 2014) (excluding "arguments contrary to the Court's claim construction... Plaintiff cannot argue that prior to transplantation actually means prior to packaging."); see also Schuyleman v. Barnhart Crane & Rigging Co., No.

23-562, 2025 WL 1414087, at *19–20 (W.D. Wash. May 15, 2025) ("Once a district court has construed the relevant claim terms, and unless altered by the district court, then that legal determination governs for purposes of trial. Thus, any expert testimony must adhere to the court's claim constructions and must not apply alternative claim constructions." (cleaned up)); *BMC Software, Inc. v. Servicenow, Inc.*, C.A. No. 14-903, 2016 WL 367251, at *2 (E.D. Tex. Jan. 29, 2016) ("no experts are to render any conclusions regarding the scope of the patents-in-suit or particular claim limitations that contradict or deviate from this Court's Claim Construction Memorandum and Order"); *EVM Sys., LLC v. Rex Med., L.P.*, C.A. No. 13-184, 2015 WL 11089476, at *2 (E.D. Tex. June 10, 2015) (granting motion to exclude "claim construction issues or arguments contradicting the Court's Claim Construction Order.").

III. WITNESS IMPEACHMENT WITH PRIOR STATEMENT

Natera proposed in the draft Cover Pleading that where a party seeks to impeach a witness by prior testimony, "The allegedly impeaching testimony must be identified to the Court and opposing counsel and shown to the witness before it is read or displayed to any jury."

Labcorp rejected this proposal, suggesting that the Court and the parties should address the mechanism for prior-statement impeachment during trial.

Natera respectfully submits that the rules should be set before trial, and should prohibit trial by ambush. Confronting a witness with a prior statement that is not, in fact, inconsistent with the witness's in-court testimony sows jury confusion and creates unwarranted tension and the baseless impression of dishonesty. Natera submits that before a witness is impeached with a putatively inconsistent prior statement, the testimony should be shown to opposing counsel and the Court for determination whether the in-court and out-of-court statements are actually inconsistent and then, if so, to the witness so that the witness can see the prior testimony and be ready to answer questions about it. See Jazz Pharm. Inc. v. Avadel CNS Pharm., LLC, C.A. No.

21-691-GBW, D.I. 545 (Oral Order) (D. Del. Feb. 20, 2024) (holding that deposition testimony of a witness testifying live at trial may be used for impeachment purposes only and "[o]nly if the witness answers a question inconsistent with the prior deposition testimony may Avadel use video excerpts of the prior deposition testimony for impeachment purposes."); *see also United States v. Hale*, 422 U.S. 171, 176 (1975) ("A basic rule of evidence provides that prior inconsistent statements may be used to impeach the credibility of a witness. As a preliminary matter, however, the court must be persuaded that the statements are indeed inconsistent."); F.R.E. 613(a) ("When examining a witness about the witness's prior statement... the party must, on request, show it or disclose its contents to an adverse party's attorney.").

IV. REFERENCE TO UNRELATED LITIGATION

Natera recently lost a jury trial in California brought by Guardant Health, Inc., in which Natera was found by the jury to have engaged in false advertising. The damages award was \$292.5 million, of which \$175.5 million represented punitive damages. *See Guardant Health, Inc. v. Natera, Inc.*, C.A. No. 21-04062, D.I. 847 (Verdict Form) (N.D. Cal. Nov. 25, 2024). There has also been press coverage of sanctions proceedings against Natera and its counsel in that case.

Natera asked Labcorp whether it intends to try to introduce anything having to do with the *Guardant* litigation during the trial of this case, expecting that the answer would be "no," given that the lawsuits are unrelated and reference to the *Guardant* case would unfairly prejudice the jury. Labcorp's answer was not an unqualified "no." Instead, Labcorp asserted that it was considering introducing not only the *Guardant* litigation but also other, unspecified prior litigation results involving Natera, but not in Labcorp's case-in-chief. Labcorp said it would seek to introduce that evidence only if Natera "opened the door" by describing its—to use Labcorp's counsel's phrase—"good hygiene." Labcorp declined to explain that phrase further, identify any specifics as to what it thinks might constitute opening the door, list what evidence it would seek

to admit, or agree in advance to any procedures by which it would warn Natera or the Court that it believed that evidence had become fair game.

There is nothing about the *Guardant* litigation that could be relevant here at all. That Labcorp does not want to identify what other such evidence it might seek to admit suggests that none of that evidence is relevant either, whatever it is. But if Labcorp intends, under any circumstances, to introduce what is essentially bad character evidence against Natera, Natera requests that the parties and the Court discuss this at the pretrial conference to hear exactly what evidence Labcorp would try to admit, and under exactly what circumstances, so the ground rules can be clear for all parties before the trial. To allow Labcorp itself to decide when, in its view, a door has been opened, and then to seek to admit bad-acts evidence in open Court with no warning, risks jury confusion and prejudice at best, and a mistrial at worst.

V. GEORGE GEMELOS AS A TRIAL WITNESS

George Gemelos, Natera's Senior Vice President of Research and Development, will be one of Natera's trial witnesses. The R&D witnesses at Natera who were deposed—Dr. Raheleh Salari and Dr. Hsin-Ta Wu—both left Natera not long after the end of the discovery period. Dr. Gemelos's testimony would address the accused product, SignateraTM, its research and development, and its functionality, including the specific portions of SignateraTM that Labcorp accuses of infringement. Dr. Gemelos will address the subject matter that would have been addressed by Drs. Salari and Wu but for their departures from Natera, including the subject matter for which Dr. Salari was designated to testify as Natera's corporate witness under Rule 30(b)(6). Both Drs. Salari and Wu live in California, outside of the Court's trial subpoena power. As a result, Natera promptly added Dr. Gemelos to its Rule 26(a)(1) disclosure and put him on Natera's witness list in January 2024, before Invitae's bankruptcy caused a trial adjournment. At the time, Natera offered to produce Dr. Gemelos for deposition.

In the twenty (20) months since then, Labcorp declined to request a deposition or further press its objection to Dr. Gemelos's inclusion in Natera's Rule 26(a)(1) disclosure. It did not identify any information it needed in any way. (Dr. Gemelos was not one of the parties' agreed-upon document custodians, and Labcorp never identified anything additional it claims to have needed.) To be clear, at then-Invitae's request, the case had not been stayed; if Invitae or Labcorp felt they needed something, they had over a year to ask for it. Indeed, in meet and confers this week, Labcorp declined Natera's offer to depose Dr. Gemelos in Wilmington the week before trial.

Instead, Labcorp seeks to capitalize on its own inaction by seeking to preclude Natera from calling, and to deprive the jury of the chance to hear from, a live Natera witness on a core issue in the case. That is baseless. Deponents leave companies sometimes. The right thing to do when that happens is promptly identify a replacement. That is exactly what Natera did with Dr. Gemelos.

VI. ISSUES FOR THE COURT

Certain issues before the Court, including certain issues presented in Natera's summary judgment motions, are issues of law for the Court to resolve, either before or after the jury trial.

Natera wishes to discuss with the Court how the Court prefers to address these issues.

A. Natera's Section 101 Argument

Natera has asserted that the Asserted Claims of the Asserted Patents do not meet the requirements of 35 U.S.C. § 101. *See, e.g.*, C.A. No. 1:21-cv-699, D.I. 31 at ¶ 33; *see generally* C.A. No. 1:21-cv-1635, D.I. 8 at ¶ 45. Satisfaction of this requirement is "ultimately an issue of law" to be decided by the Court. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1365 (Fed. Cir. 2018), *cert. denied*, 140 S. Ct. 911 (2020). The Court previously denied Natera's motion to dismiss under Fed. R. Civ. P. 12(b)(6), in which Natera argued that all claims of the '799 patent are directed to an abstract idea and unpatentable under Section 101. C.A. No. 1:21-cv-699, D.I. 28 at 3–7. The Court held that Natera failed at Step One of the *Alice* test, finding that representative Claim 1 of

the '799 patent is, as Labcorp (then, Invitae) had argued, "directed to a 'technological solution to the technological problem of how to better assemble DNA sequences [...] in a more computationally efficient and overall improved way." *Id.* at 4–5. But the record that developed subsequently, including inventor testimony and arguments made by Labcorp, shows that the Asserted Claims are not directed to "a specific solution to a technological problem in the field of sequence assembly," as the Court previously found at the motion-to-dismiss stage. Labcorp has moved in *limine* to preclude Natera from advancing this defense, despite not having sought summary judgment on the issue. *See* Labcorp Motion *in Limine* No. 1. Natera would like to discuss with the Court the manner and timing of the presentation of evidence, and a ruling thereon, concerning its challenge to the subject matter eligibility of the Asserted Claims during the Pretrial Conference.

B. Natera's Claim Vitiation Argument

Natera has asserted that Labcorp's theory of infringement under the doctrine of equivalents fails because Labcorp's equivalence theory would vitiate one or more claim elements of the Asserted Claims of the Asserted Patents. Whether a patentee's theory of equivalence, in light of the claim language and alleged evidence of infringement, would vitiate the claim limitations is a legal conclusion to be resolved by the Court. *See Bio-Rad Lab'ys, Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1367, 1371–72 (Fed. Cir. 2020); *see also, e.g., Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997) ("[I]f a theory of equivalence would entirely vitiate a particular claim element, partial or complete judgment should be rendered by the court, as there would be no further material issue for the jury to resolve."). Natera's motion for summary judgment on this issue is pending before the Court. *See* D.I. 222, 223, 227, 227-1, 246, 248, 250, 262, 266, 267.

C. Natera's Ensnarement Argument

Natera has asserted that Labcorp's equivalence theory also fails because it would encompass or "ensnare" the prior art. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1322–23 (Fed. Cir. 2009). "This limitation is imposed even if a jury has found equivalence as to each claim element." *Id.* (citing *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 683, 687 (Fed. Cir. 1990), *overruled in part on other grounds, Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 92 n.12 (1993)). "[E]nsnarement is a legal question for the district court to decide." *G. David Jang, M.D. v. Bos. Sci. Corp.*, 872 F.3d 1275, 1288 (Fed. Cir. 2017); *see also DePuy Spine*, 567 F.3d at 1324 (holding ensnarement is "to be determined by the court, either on a pretrial motion for partial summary judgment or on a motion for judgment as a matter of law at the close of the evidence and after the jury verdict") (quoting *Warner-Jenkinson*, 520 U.S. at 39 n.8). To the extent there is any finding of infringement under the doctrine of equivalents, Natera asks that the issue be addressed in connection with post-trial briefing, supported by expert declarations, and an evidentiary hearing.

VII. CASE NARROWING

Natera responds briefly to Labcorp's discussion of this issue in its Statement of Additional Matters.

The parties have engaged in substantial back-and-forth in an effort to reach agreement on case narrowing. Thus far, the parties have agreed that Labcorp will narrow its number of asserted claims to ten. The parties have also agreed that Natera will narrow its invalidity defenses to three prior-art grounds and three non-prior-art grounds,

One remaining area of disagreement is whether Natera's narrowing of its invalidity defenses should be on a per-claim or per-patent basis. Natera's position is that its defense-narrowing should be on a per-claim basis because, as it has explained to Labcorp, some of the

dependent claims add limitations that may require or give rise to additional invalidity defenses, separate and apart from the claims from which they depend.

The parties also disagree about whether asserting that the same prior-art reference both anticipates a claim and renders that claim obvious (without being read in combination with any other references) should count as one or two prior-art defenses. Natera's position is that anticipation and single-reference obviousness based on the same reference should count as one ground for purposes of narrowing, because the evidence and arguments for anticipation and single-reference obviousness are almost entirely overlapping. Labcorp has refused to agree, but has not explained why beyond stating that "single-reference obviousness and anticipation are two different theories of invalidity that require different proofs."

To the extent that the Court issues any order regarding case narrowing, Natera respectfully requests that Labcorp be ordered to narrow to no more than 10 asserted claims and that Natera be ordered to narrow to no more than three prior art grounds per claim, where anticipation and single-reference obviousness based on the same reference count as one ground, and three non-prior art grounds per claim.

VIII. LABCORP'S UPDATED FINANCIAL INFORMATION

Natera has requested that Labcorp produce updated financial information, through November 2023, for its PCM product, which is the product that Labcorp contends competes with Signatera[™] and forms the basis for Labcorp's lost profits claim. Labcorp has not yet responded to Natera's request, but from the parties' recent meet and confer sessions, Natera expects that Labcorp will agree to this request. Out of an abundance of caution Natera is including this issue here, so that if Labcorp refuses to provide updated financial information, the parties and the Court may address this issue at the Pretrial Conference.

Exhibit 16

IX. IDENTIFICATION OF EXHIBIT NUMBERS USED IN DEMONSTRATIVES

Natera proposed in the draft Cover Pleading that the parties identify by number any exhibits that they rely on in their demonstratives. Specifically, Natera proposed that "[e]ach demonstrative exhibit shall identify by exhibit number all trial exhibits that form the basis of the demonstrative exhibit. Such identified trial exhibits referenced in the demonstrative exhibit and shown to a witness may be offered into evidence during or at the conclusion of the examination for the witness with whom the demonstratives were used." Natera's proposal aimed to streamline the presentation of issues at trial and limit confusion by requiring that the parties specify what exhibits are excerpted, cited, or summarized in their demonstratives. Labcorp did not agree with Natera's proposal, because it was concerned that it would not be able to tell whether and when exhibits would need to be cited for demonstratives that disclose generic concepts. Natera respectfully requests that the Court address this issue at the Pretrial Conference, and hold that, to the extent that a party's demonstrative quotes, excerpts, summarizes, or depicts one or more exhibits, the party is required to identify by exhibit number all trial exhibits that form the basis of the demonstrative exhibit.

EXHIBIT 17A



ALEXANDER L. CLEMONS CURRICULUM VITAE

January 23, 2024

Alexander L. Clemons is a Managing Director at Ocean Tomo, LLC, a part of J.S. Held. Ocean Tomo provides Financial Expert, Management Consulting, and Advisory services related to intellectual property ("IP") and other intangible assets, corporate accounting investigations, regulatory and reporting obligations, solvency and restructuring, and contractual or competition disputes. Practice offerings address economic damage calculations and testimony, accounting investigations and financial forensics, technology and intangible asset valuation, strategy and risk management consulting, mergers and acquisitions, debt and equity private placement, and IP brokerage. Subsidiaries of Ocean Tomo include Ocean Tomo Investments Group, LLC, a registered broker dealer. With more than 100 offices globally, J.S. Held assists clients—corporations, insurers, law firms, governments, and institutional investors—on complex technical, scientific, and financial matters across all assets and value at risk.

Mr. Clemons works in Ocean Tomo's Intellectual Property Disputes Financial Expert Testimony practice. This practice area quantifies economic damages arising from intellectual property disputes and provides general litigation support. Mr. Clemons has extensive experience related to the assessment of economic damages in litigation matters involving intellectual property, breach of contract, and other claims. He has been retained as a damages expert on many engagements, providing written, deposition, arbitration, and trial testimony. Outside of a litigation context, Mr. Clemons has experience with intellectual property valuation and has provided analytical support to clients engaged in licensing negotiations and other transactions.

Mr. Clemons has assisted clients in numerous engagements involving the valuation of intellectual property and the determination of economic damages in commercial suits, including patent infringement, trademark infringement, copyright infringement, trade secret misappropriation, technology misappropriation, and breach of contract litigation. He possesses a solid understanding of the financial issues and theories related to the quantification of damages in litigation. While specific issues vary by engagement, most have included evaluation and analysis of financial and strategic data to support or rebut quantification of lost profits, reasonable royalties, price erosion, unjust enrichment, commercial success, and/or business valuation. Mr. Clemons has supported counsel in all phases of the litigation process from discovery to trial, and his experience spans a wide variety of industries, including pharmaceuticals, medical devices, medical diagnostics, laboratory instruments and reagents, healthcare services, healthcare data, telecommunications, semiconductors, consumer electronics, smart phones, software, gaming, VR/AR, e-commerce, consumer goods, food products, dietary supplements, chemical products, automotive, entertainment, financial services, insurance, firearms, military and aviation technologies, airport security, and ventilation products, among others.

Mr. Clemons graduated with Academic Excellence from the University of Illinois, Urbana-Champaign, with an MBA concentrated in Finance. He graduated *cum laude* from DePaul University, College of Law, with a JD. He also holds a Bachelor of Arts in Rhetoric from the University of Illinois, Urbana-Champaign.

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EDUCATION

University of Illinois, MBA, Concentration in Finance, Graduated with

MBA Academic Excellence Award

DePaul University College of Law, JD, Graduated cum laude

University of Illinois, BA, Rhetoric

BAR ADMISSION

State of Illinois

November 2010

EXPERIENCE

Managing Director, Ocean Tomo

January 2022 to Present

Senior Director, Ocean Tomo

January 2021 to December 2021

Director, Ocean Tomo

July 2016 to December 2020

Associate, Ocean Tomo

January 2014 to June 2016

Analyst, Ocean Tomo

March 2013 to December 2013

Attorney, Dodd & Maatuka, LLC

May 2011 to March 2013

Law Clerk, Jeffrey M. Goldberg Law Offices

June 2008 to May 2010

MEMBERSHIPS

American Bar Association

Illinois State Bar Association

Intellectual Property Law Association of Chicago

PUBLICATIONS

"Role of Patent Expert in Antitrust Litigation." Lexology, January 19, 2022.

"Uncertainty in Awarding Defendant's Profits in Lanham Act Cases after

Romag." Landslide, June 2020. With Cate Elsten.



"Separating 'Pay' from 'Delay': Fairness Opinions of Reverse Payment Settlements under *Actavis* and Its Progeny." *Landslide*, July 2015.

"Apportionment in Reasonable Royalty Damages." ABA 30th Intellectual Property Law Conference, March 2015. With Andrew Carter.

"Beyond the Smallest Salable Unit: How Surveys Provide a Path from Recent Case Law to an Appropriate Royalty Base." *Landslide*, May 2014.

ENGAGEMENTS SERVING AS EXPERT (client in italics)

Invitae Corporation v. Natera, Inc.

Civil Action Nos. 1:21-cv-00669 & 1:21-cv-01635

Cases Filed: 05/07/2021 & 11/21/2021 U.S. District Court for the District of Delaware

Claim(s): Patent Infringement

Testimony: Expert Report, Deposition

Photography By Frank Diaz LLC v. Friends of David Schweikert, et al

Civil Action No. 2:22-cv-01170

Case Filed: 07/13/2022

U.S. District Court for the District of Arizona

Claim(s): Copyright Infringement

Testimony: Expert Report

Fortress Iron L.P. v. Digger Specialties, Inc.

Civil Action No. 3:21-cv-00014

Case Filed: 01/08/2021

U.S. District Court for the Northern District of Indiana

Claim(s): Patent Infringement

Testimony: Expert Report, Deposition

SecurityPoint Holdings, Inc., v. The United States

Civil Action No. 1:11-cv-00268

Case Filed: 05/02/2011 U.S. Court of Federal Claims

Claim(s): Patent Infringement Under 28 U.S.C. § 1498

Testimony: Expert Report, Deposition

Lyft, Inc., v. Quartz Auto Technologies LLC

Civil Case No. 4:21-cv-01871 Case Filed: 03/17/2021

U.S. District Court for the Northern District of California

Claim(s): Patent Infringement, Declaratory Judgment

Testimony: N/A



W. R. Grace & Co.-Conn. v. Elysium Health, Inc.

Civil Case No. 1:20-cv-01098 Case Filed: 08/21/2020

U.S. District Court for the District of Delaware

Claim(s): Patent Infringement

Testimony: Expert Report, Deposition, Trial

Central Texas Pain Center PLLC, et al., v. Eric J. Miller, M.D., et al.

Arbitration No. 01-21-0018-0513 American Arbitration Association Claim(s): Breach of Contract Testimony: Expert Report

DuraSystems Barriers, Inc. v. Van-Packer Co. and Jeremias, Inc.

Civil Case No. 1:19-cv-01388 Case Filed: 12/03/2019

U.S. District Court for the Central District of Illinois

Claim(s): Patent Infringement

Testimony: Expert Report, Deposition

Makina ve Kimya Endustrisi Kurumu v. Kutlay Kaya, et al.

Civil Action No. 3:20-cv-00072

Case Filed: 11/24/2020

U.S. District Court for the Western District of Virginia Claim(s): Trademark Infringement, False Advertising, Unfair

Competition, Breach of Contract

Testimony: Expert Report, Deposition, Trial

Combined Insurance Company of America v. Family Heritage Life Insurance Company of America, et al.

Arbitration No. 01-20-0010-8869 American Arbitration Association

Claim(s): Breach of Contract, Tortious Interference, and Breach of

Fiduciary Duty

Testimony: Expert Report, Deposition, Arbitration

ChromaDex, Inc., et al., v. Elysium Health, Inc.

Civil Action No. 1:18-cv-01434

Case Filed: 09/17/2018

U.S. District Court for the District of Delaware

Claim(s): Patent Infringement

Testimony: Expert Report, Deposition



American River Nutrition, LLC, v. Kyäni, Inc.

Civil Action No. 4:19-cv-00255

Case Filed: 07/08/2019

U.S. District Court for the District of Idaho

Claim(s): Patent Infringement

Testimony: Expert Report, Deposition (single deposition for both

American River Nutrition matters)

American River Nutrition, LLC, v. Beijing Gingko Group Biological Technology Co., Ltd. et al.

Civil Action No. 8:18-cv-02201

Case Filed: 12/12/2018

U.S. District Court for the Central District of California

Claim(s): Patent Infringement

Testimony: Expert Report, Deposition (single deposition for both

American River Nutrition matters)

Otto Brands, LLC, et al., v. Otto's Express Car Wash, LLC, et al.

Civil Action No. 3:19-cv-00572

Case Filed: 04/11/2019

U.S. District Court for the Northern District of Florida

Claim(s): Trademark Infringement, Unfair Competition, False Designation of Origin, Anti-Cybersquatting, and False Advertising

Testimony: Expert Report

Auto Konnect, LLC, v. BMW of North America, LLC, et al.

Civil Action No. 2:18-cv-14019

Case Filed: 12/21/2018

U.S. District Court for the Eastern District of Michigan

Claims(s): Breach of Contract and Breach of the Implied Covenant of

Good Faith and Fair Dealing

Testimony: Expert Report, Deposition, Trial

Halosil International, Inc., et al., v. Eco-Evolutions, LLC, et al.

Civil Action No. 1:18-cv-01375

Case Filed: 09/05/2018

U.S. District Court for the District of Delaware Claims(s): Breach of Contract and False Advertising

Testimony: Expert Report, Deposition

Virginia Vallejo v. Narcos Productions LLC, et al.

Civil Action No. 1:18-cv-23462

Case Filed: 08/24/2018

U.S. District Court for the Southern District of Florida

Claims(s): Copyright Infringement

Testimony: Expert Report



Palm Partners, LLC, v. National Association of Addiction Treatment Providers

Civil Action No. 9:18-cv-81638 Case Filed: 11/30/2018

U.S. District Court for the Southern District of Florida

Claim(s): Defamation, Trade Libel, and Tortious Interference with

Prospective Economic Advantage

Testimony: Expert Report

Gary James v. OneUnited Bank, N.A., et al.

Civil Action No. 1:17-cv-24415

Case Filed: 12/06/2017

U.S. District Court for the Southern District of Florida

Claim(s): Copyright Infringement Testimony: Expert Report, Deposition

Genedics, LLC, v. Leap Motion, Inc.

Civil Action No. 1:18-cv-00265

Case Filed: 02/15/2018

U.S. District Court for the District of Delaware

Claim(s): Patent Infringement

Testimony: N/A

Umbanet, Inc., v. Epsilon Data Management, LLC

Civil Action No. 2:16-cv-00682 Case Filed: 06/23/2016

U.S. District Court for the Eastern District of Texas

Claim(s): Patent Infringement

Testimony: N/A

ENGAGEMENTS
ASSISTING OTHER
OCEAN TOMO
EXPERTS
(client in italics)

Novartis Pharma AG, et al., v. Regeneron Pharmaceuticals, Inc.

Civil Action No. 1:20-cv-00690

U.S. District Court for the Northern District of New York

Claim(s): Patent Infringement

hiQ Labs, Inc. v. LinkedIn Corporation

Civil Action No. 3:17-cv-03301

U.S. District Court for the Northern District of California

Claim(s): Declaratory Judgment, Intentional Interference with Contract and Prospective Economic Advantage, Unfair Competition, Computer Fraud and Abuse Act, California Comprehensive Computer Access and Fraud Act, Breach of Contract, Misappropriation, Trespass to Chattels



Mexichem Amanco Holding, S.A. de C.V. v. The Chemours Company, et al.

Civil Action No. 4:20-cv-01960 U.S. District Court for the Southern District of Texas Claim(s): Patent Infringement

Roche Diabetes Care, Inc., v. Insulet Corporation

Civil Action No. 1:20-cv-00825 U.S. District Court for the District of Delaware Claim(s): Patent Infringement

Regeneron Pharmaceuticals, Inc., v. Novartis Pharma AG, et al.

Case IPR2021-00816 United States Patent and Trademark Office Claim(s): Patent Invalidity

Arbitration No. 01-21-0002-6106

Baxter International Inc., et al., v. CyDex Pharmaceuticals, Inc., et al.

American Arbitration Association Claim(s): Breach of Contract, Declaratory Judgment, Breach of Implied Covenant of Good Faith and Fair Dealing

PureCircle USA Inc., et al., v. SweeGen, Inc., et al.

Civil Action No. 8:18-cv-01679 U.S. District Court for the Central District of California Claim(s): Patent Infringement

Crocs, Inc., v. Effervescent, Inc., et al.

Civil Action No. 1:06-cv-00605 U.S. District Court for the District of Colorado Claim(s): False Advertising, Patent Infringement

Cisco Systems, Inc., et al., v. Jedd Williams

Arbitration No. 1310025030 JAMS Arbitration

Claim(s): Misappropriation of Trade Secrets, Breach of Contract, Breach of Fiduciary Duty, Breach of the Implied Covenant of Good Faith and Fair Dealing

Aliign Activation Wear, LLC, v. lululemon usa inc., et al.

Civil Action No. 2:20-cv-03339 U.S. District Court for the Central District of California Claim(s): Trademark Infringement, False Designation of Origin, and Unfair Competition



Huawei Technologies Co. Ltd., v. Verizon Communications, Inc., et al.

Civil Action No. 2:20-cy-00030

U.S. District Court for the Eastern District of Texas Claim(s): Patent Infringement, RAND Obligations

Bio-Rad Laboratories, Inc., et al., v. 10X Genomics, Inc.

Civil Action No. 1:19-cv-12533

U.S. District Court for the District of Massachusetts

Claim(s): Patent Infringement and Antitrust Violation of Section 2 of the

Sherman Act and Section 7 of the Clayton Act

Bio-Rad Laboratories, Inc., et al., v. Stilla Technologies, Inc., et al.

Civil Action No. 1:19-cv-11587

U.S. District Court for the District of Massachusetts

Claim(s): Patent Infringement

In the Matter of Certain Pre-filled Syringes for Intravitreal Injection and Components Thereof

Investigation No. 337-TA-1207

U.S. International Trade Commission

Claims(s): Patent Infringement

ICON Health & Fitness, Inc., v. Peloton Interactive, Inc.

Civil Action No. 1:20-cv-01386

U.S. District Court for the District of Delaware

Claim(s): Patent Infringement

CareDx, Inc., v. Natera, Inc.

Civil Action No. 1:19-cv-00662

U.S. District Court for the District of Delaware

Claim(s): False Advertising, Unfair Competition, and Unfair or

Deceptive Trade Practices

Match Group, LLC, v. Bumble Trading Inc., et al.

Civil Action No. 6:18-cv-00080

U.S. District Court for the Western District of Texas

Claim(s): Patent Infringement, Trademark Infringement, Trade Dress

Infringement, Trademark Dilution, Unfair Competition, and

Misappropriation of Trade Secrets

Sanyo Electric Co., Ltd., v. Intel Corporation

Civil Action No. 2018-0723

Court of Chancery of the State of Delaware

Claim(s): Declaratory Judgment of Parties' Contractual Rights, Request

for Contract Reformation, and Breach of Contract



Allscripts Healthcare, LLC, v. DR/Decision Resources, LLC d/b/a Decision Resources Group

Civil Action No. 1:19-cv-11038

U.S. District Court for the District of Massachusetts

Claim(s): Misappropriation of Trade Secrets, Breach of Contract, Unfair

and Deceptive Trade Practices, and Fraudulent Inducement

Illumina, Inc., v. Natera, Inc.

Civil Action No. 3:18-cv-01662

U.S. District Court for the Northern District of California

Claim(s): Patent Infringement

In the Matter of Certain Botulinum Toxin Products, Processes for Manufacturing or Relating to Same and Certain Products Containing Same

Investigation No. 337-TA-1145

U.S. International Trade Commission

Claims(s): Misappropriation of Trade Secrets

SecurityPoint Holdings, Inc., v. The United States

Civil Action No. 1:11-cv-00268

U.S. Court of Federal Claims

Claim(s): Patent Infringement Under 28 U.S.C. § 1498

Plexxikon, Inc., v. Novartis Pharmaceuticals Corporation

Civil Action No. 4:17-cv-04405

U.S. District Court for the Northern District of California

Claim(s): Patent Infringement

The Gillette Company v. Dollar Shave Club, Inc. et al.

Civil Action No. 1:15-cv-01158

U.S. District Court for the District of Delaware

Claim(s): Patent Infringement

Inguran, LLC, d/b/a STGenetics, et al., v. ABS Global, Inc., et al.

Civil Action No. 3:17-cv-00446

U.S. District Court for the Western District of Wisconsin

Claim(s): Patent Infringement

Masterbuilt Manufacturing, LLC, v. Wal-Mart Stores, Inc.

Civil Action No. 4:17-cv-00213

U.S. District Court for the Middle District of Georgia

Claim(s): Patent Infringement

Gilead Sciences, Inc., v. Roche Molecular Systems, Inc.

Arbitration No. 01-16-0004-7625

American Arbitration Association

Claim(s): Breach of Contract



Optical Air Data Systems, LLC, v. L-3 Communications Corp., Display Systems Division, et al.

Civil Action No. N17C-05-619 Superior Court of the State of Delaware

Claim(s): Breach of Contract

Acantha LLC v. DuPuy Orthopaedics Inc., et al.

Civil Action No. 1:15-cv-01257

U.S. District Court for the Eastern District of Wisconsin

Claim(s): Patent Infringement

Verinata Health, Inc., et al., v. Ariosa Diagnostics, Inc., et al.

Civil Action No. 3:12-cv-05501

U.S. District Court for the Northern District of California

Claim(s): Patent Infringement

Lotes Co., Ltd., v. Hon Hai Precision Industry Co., Ltd., et al.

Civil Action No. 3:11-cv-01036

U.S. District Court for the Northern District of California

Claim(s): Patent Infringement, Breach of Contract, and Underpayment

of Royalties

RainDance Technologies, Inc., et al., v. 10X Genomics, Inc.

Civil Action No. 1:15-cv-00152

U.S. District Court for the District of Delaware

Claim(s): Patent Infringement

Shuffle Tech International LLC, et al., v. *Scientific Games Corporation*, et al.

Civil Action No. 1:15-cv-03702

U.S. District Court for the Northern District of Illinois

Claim(s): Antitrust Violation of Section 2 of the Sherman Act and

Section 7 of the Clayton Act

Idenix Pharmaceuticals LLC, et al., v. Gilead Sciences, Inc.

Civil Action No. 1:14-cv-00846

U.S. District Court for the District of Delaware

Claim(s): Patent Infringement

Gilead Sciences, Inc., v. Merck & Co., Inc., et al.

Civil Action No. 5:13-cv-40572

U.S. District Court for the Northern District of California

Claim(s): Patent Infringement

Actavis Laboratories UT, Inc. v. UCB, Inc.

Civil Action No. 2:15-CV-01001

U.S. District Court for the Eastern District of Texas

Claim(s): Patent Infringement



Sanofi-Aventis U.S. LLC, et al., v. Genentech, Inc., et al.

Civil Action No. 2:15-cv-05685

U.S. District Court for the Central District of California

Claim(s): Patent Infringement

Advanced Aerospace Technologies, Inc., v. The United States, et al.

Civil Action No. 1:12-cv-00085

U.S. Court of Federal Claims

Claim(s): Patent Infringement Under 28 U.S.C. § 1498

Fujitsu Limited v. Tellabs, Inc., et al.

Civil Action No. 1:09-cv-04530

U.S. District Court for the Northern District of Illinois

Claim(s): Patent Infringement, RAND Obligations

Mitsubishi Electric Corp., et al., v. Sceptre, Inc.

Civil Action No. 2:14-cv-04994

U.S. District Court for the Central District of California

Claim(s): Patent Infringement of Standard Essential Patents

Zenith Electronics LLC, et al., v. Sceptre, Inc.

Civil Action No. 2:14-cv-05150

U.S. District Court for the Central District of California

Claim(s): Patent Infringement of Standard Essential Patents

Rembrandt Social Media, LP, v. Facebook, Inc., et al.

Civil Action No. 1:13-cv-00158

U.S. District Court for the Eastern District of Virginia

Claim(s): Patent Infringement

Zecotek Imaging Systems Pte. Ltd. v. Saint-Gobain Ceramics & Plastics, Inc., et al.

Civil Action No. 5:12-cv-01533

U.S. District Court for the Northern District of Ohio

Claim(s): Patent Infringement

GSI Technology, Inc., v. United Memories, Inc., et al.

Civil Action No. 5:13-cv-01081

U.S. District Court for the Northern District of California

Claim(s): Breach of Contract, Unfair Competition, Fraud,

Misappropriation of Trade Secrets, and Intentional Interference with

Prospective Economic Advantage



Dalmatia Import Group, Inc., et al., v. FoodMatch, Inc., et al.

Civil Action No. 2:16-cv-02767

U.S. District Court for the Eastern District of Pennsylvania Claim(s): Misappropriation of Trade Secrets, Breach of Contract, Unfair Competition, Tortious Interference with Contract, Trademark Infringement, Trademark Counterfeiting, and Conversion

Kuryakyn Holdings, LLC, v. Ciro, LLC, et al.

Civil Action No. 3:15-cv-00703

U.S. District Court for the Western District of Wisconsin Claim(s): Misappropriation of Trade Secrets, Copyright Infringement, Unfair Competition and False Advertising, Breach of Contract, Breach of Fiduciary Duty, Unfair Competition, and Conversion

CONTACT

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Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 324 of 739 PageID

EXHIBIT 17B

Curriculum Vitae

A. NAME Joshua P. Earl

B. PROFESSIONAL MAILING ADDRESS

Professional Address:

Department of Microbiology and Immunology Center for Genomic Sciences Drexel University College of Medicine 245 N. 15th Street Philadelphia, PA 19102

C. EDUCATION

2014-2018

PhD in Biomedical Sciences, Concentration in Bioinformatics Drexel University, Philadelphia PA 19102

2007-2009

MS in Computational Biology Carnegie Mellon University, Pittsburgh PA 15213 Completed: Dec 2009

2001-2004

BS Major: Environmental Studies/Biology, Minor: Philosophy

St. Lawrence University, Canton NY 13617 Awarded: May 16, 2004 Honors: Cum Laude

2000-2001

A.A.S. Computer Information Technology SUNY Canton, Canton NY 13617

1998-1999

Computer Science

Clarkson University, Potsdam NY

D. EMPLOYMENT HISTORY

2022-Present

Assistant Professor, Director of Clinical and Translational Bioinformatics

Drexel University College of Medicine, 245 N Broad St. Philadelphia PA 19102. All previous responsibilities at this institution. Additionally, increased management responsibility for new laboratory information management system (LIMS) design, implementation, and management, including overseeing new database administrator and additional bioinformatics programming personnel. Further development of bioinformatics pipelines to be used by the new Clinical Laboratory Improvements Amendments (CLIA) and College of American Pathologists (CAP) certified Drexel Medicine Diagnostics Laboratory, including novel new tests such as Lyme Disease infection, full-length 16S-based microbiome test, and 18S ribosomal region human-associated fungal species test.

2020-2022

Assistant Professor, Director of Bioinformatics

Drexel University College of Medicine, 245 N Broad St. Philadelphia PA 19102 Primarily the same responsibilities of the previous Research Instructor position, however new added responsibilities include overseeing the technical computer hardware/software development of a new COVID-19 testing lab. This included creating software to automatically interpret output of high throughput PCR Quantstudio machine tests, and workflow to integrate data into multiple health system and laboratory information systems. I also wrote and implemented standard operating procedure (SOP) creation and validation for laboratory information management systems (LIMS) for CLIA certification. Workflow development for all sequencers to final datasets and reports, which includes whole genome (bacterial) sequencing on Pacific Biosciences Sequel and Illumina Miseq/Nextseq assembly pipelines, a novel highly accurate microbiome sequencing to organism identification using Pacbio Sequel, pipeline implementation of COVID-19 strain identification using Pacbio Sequel, and currently developing a new novel fungal microbiome identification pipeline to match the same degree of granularity as our bacterial microbiome identification pipeline. In addition to doing lectures for multiple graduate level courses (phylogenetics, database information mining), I also run two weekly education clubs teaching statistical analysis in the R framework and using the Linux operating system for scientific research.

2013-2020

Research Instructor, Director of Bioinformatics

Drexel University College of Medicine, 245 N Broad St. Philadelphia PA 19102 Responsible for bioinformatics software and hardware development to support new Genomic Sequencing Center. Oversee bioinformatics programming group (2 bioinformatics programmers), graduate student mentorship in bioinformatics and assist teaching bioinformatics graduate classes. Continuing management, support and independent development of all bioinformatics research and analysis in prokaryote and eukaryote sequencing efforts. DNA sequencing technologies overseen include Pacific Biosciences RSII, Pacific Biosciences Sequel, Illumina Nextseq, and Roche Life Sciences 454. Management and system administration of Centos 6 Linux cluster computing system for DNA sequencing analysis and support for department. Development of multiple analysis pipelines for NGS (next generation sequencing) data analysis, including a novel 16S whole gene sequencing and clustering analysis pipeline in Ruby and R, whole genome assembly and annotation, and comparative genomic analysis pipelines for bacterial genomes using statistical techniques, transcriptome analysis with RNAseq.

2010-2013

Assistant Professor, Director of Bioinformatics:

Center for Genomic Sciences, Allegheny-Singer Research Institute, Pittsburgh, PA Responsible for the setup and continued maintenance of over 10 Windows/Linux servers for genomic analysis/data storage (including virtualized environments for specific analyses using both Hyper-V and VirtualBox). Oversaw installation and implementation of current generation sequencing technology of the Pacific Biosciences RS sequencer, both software and hardware. Developed pipelines for whole genome assembly and comparative genome analysis using current computational algorithms tailored for two sequencing methodologies (Roche 454 and Pacific Biosciences RSII). Developed programs to automate and facilitate genomic/genetic analysis for various data types. Implemented user friendly SQL database backed online tools with Ruby on Rails web application design, and database management protocol.

2008-2009

Computational Biology/Bioinformatics Programmer:

Center for Genomic Science, Allegheny-Singer Research Institute, Pittsburgh PA, Bioinformatics group. Responsible for development/maintenance of genomic analysis pipeline. Consulted/developed novel techniques for identifying horizontal gene transfer events. Developed statistical analysis of genomic data analysis for both prokaryotic/eukaryotic DNA sequence. Developed Java/Perl/R/VBA programs to automate various genomic analysis tasks, consulted on server hardware setup/use. Consulted/designed/implemented computer algorithms for sequence analysis of 2nd gen high-throughput genomics, including 454 Roche Lifesciences and Illumina sequence

2007-2008

Departmental Fellowship: Carnegie Mellon University, Pittsburgh, PA

<u>2006-2007</u>

Metrology Chemist, Pfizer/Johnson and Johnson:

Lititz, PA Quality Control Department. Responsible for calibration, maintenance, and repair of laboratory equipment on a monthly/yearly basis in microbiology, and chemistry labs. Repaired equipment ranging from relatively simple (water baths, electronic pipettes) to complex (computers, highly accurate measurement machinery). Dealt directly with vendors troubleshooting equipment, ordering parts, and scheduling vendor required calibrations.

2004-2006

Pharmaceutical Microbiology Analyst:

Lancaster Labs Inc. Performed FDA quality control testing on a variety of pharmaceutical products, including DEA controlled substances, and highly toxic compounds. Proficient in all SOP microbiological analyses ranging from total colony forming unit tests, to specific organism identification procedures (including Salmonella, Enteric, Staphylococcus, Pseudomonas, and Clostridia spp.) and helped adapt client methods to in-house testing. Responsible for environmental monitoring of BSL2 GLP compliant laboratory space, and the equipment therein. Given increased responsibility regularly during employment. Volunteered on large projects out of my department.

2004

Web Design Consultant

Town of Lisbon, N.Y. Collected information, designed, implemented and provided technical assistance for the Town of Lisbon's web site. Spring

2003-2004

Forest Ecology T.A. (Teaching Assistant)

Biology Department St. Lawrence University

General Biology T.A.

Biology Department St Lawrence University (awarded 4.0/4.0 grade)

1999-2000

Warehouse Manager Targray Inc. Responsible for all incoming/outgoing shipping for warehouse in Northern NY, including invoices, bills of lading, Material Safety Data Sheets, inventory counts, and database management.

E. HONORS AND AWARDS

Travel Award Spring 2019 International Society for Otitis Media, Hollywood CA

Departmental Fellowship: Fall 2007 Carnegie Mellon University, Pittsburgh, PA

Beta Beta Honors Society for Biology, Spring 2003-present

• Awarded for maintaining a 3.5/4.0 GPA in all Biology classes

Latin Honors: Cum Laude upon graduation from St. Lawrence University

Dean's List: St. Lawrence University Fall 2001 (Awarded for GPA > 3.62/4.0)

Phi Theta Kappa: Honors society for two year Colleges, SUNY Canton

F. Expert Witness Consulting Experience

- 1. Investigation No. 337-TA-1032 CERTAIN SINGLE-MOLECULE NUCLEIC ACID SEQUENCING SYSTEMS AND REAGENTS, CONSUMABLES, AND SOFTWARE FOR USE WITH SAME. 2016-2017
 - a. Source code review, patent review, report writing, deposition.
- C. A. No. 17-cv-275-LPS-CJB & C. A. No. 17-cv-1353-LPS-CJB Pacific Biosciences of California, Inc. v. Oxford Nanopore Technologies, Inc., No. 1:2017cv00275 - Document 152 (D. Del. 2019)
 - a. Source code review, patent review, report writing, deposition, and trial testimony.
- 3. Case No. IPR2022-01158 Guardant Health Inc. v. University of Washington IPR of '951
 - a. Source code review, patent review, report writing
- 4. Case Nos: 21-cv-669-GBW and 21-cv-1635-GBW. Invitae Corporation v. Natera, Inc.
 - a. Source code review, patent review, report writing

G. EDUCATIONAL ACTIVITIES

Teaching Experience

Classes taught on bioinformatics concepts including Linux command line usage for bioinformatics analysis, bacterial genomics and phylogenetics, omics, and usage of the R statistical package in analysis of bioinformatics. Classes include MIIM 555S Molecular Mechanisms of Microbial Pathogenesis, MIIM-620S OMICS, MIIM-542S-900 Mycology and Fungal Infections, and MIIM 513S MOLECULAR PATHOGENSIS II in the Department of Microbiology and Immunology in the Institute for Molecular Medicine and Infectious Disease. Mentoring PhD students in comparative genomics, Linux operating system command line usage, R, programming, bioinformatics programs and analysis on two pangenomics projects (Gardnerella vaginalis, and Porphyromonas gingivalis), and an investigation of HPV integration into the human genome.

H. BIBLIOGRAPHY

Published full-length papers

- 1. Su, Y.-P., Lin, S. Y., Su, I.-J., Kao, Y.-L., Shen, S.-C., **Earl, J. P.**, Ehrlich, G. D., Chen, C.-Y., Huang, W., Su, Y.-H., & Tsai, H.-W. (2024). Characterization of integrated hepatitis B virus DNA harboring pre-S mutations in hepatocellular carcinoma patients with ground glass hepatocytes. *Journal of Medical Virology*, *96*(1), e29348.
- 2. Moné, Y., Earl, J. P., Król, J. E., Ahmed, A., Sen, B., Ehrlich, G. D., & Lapides, J. R. (2023). Evidence supportive of a bacterial component in the etiology for Alzheimer's disease and for a temporal-spatial development of a pathogenic microbiome in the brain. *Frontiers in Cellular and Infection Microbiology*, 13, 1123228.
- 3. Dampier, W., Link, R. W., **Earl, J. P.**, Collins, M., De Souza, D. R., Koser, K., Nonnemacher, M. R., & Wigdahl, B. (2022). HIV- Bidirectional Encoder Representations From Transformers: A Set of Pretrained Transformers for Accelerating HIV Deep Learning Tasks. *Frontiers in Virology*, *2*. https://doi.org/10.3389/fviro.2022.880618
- 4. Nickel, J. C., Ehrlich, G. D., Krol, J. E., Ahmed, A., Sen, B., Bhat, A., Mell, J. C., Doiron, R. C., Kelly, K.-L., & Earl, J. P. (2022). The bacterial microbiota of Hunner lesion interstitial cystitis/bladder pain syndrome. *BJU International*.
- 5. Xu, L., Earl, J., & Pichichero, M. E. (2021). Nasopharyngeal microbiome composition associated with Streptococcus pneumoniae colonization suggests a protective role of Corynebacterium in young children. *PloS One*, *16*(9), e0257207.
- 6. Socarras, K. M., Earl, J. P., Krol, J. E., Bhat, A., Pabilonia, M., Harrison, M. H., Lang, S. P., Sen, B., Ahmed, A., Hester, M., Mell, J. C., Vandegrift, K., & Ehrlich, G. D. (2021). Species-Level Profiling of Ixodes pacificus Bacterial Microbiomes Reveals High Variability Across Short Spatial Scales at Different Taxonomic Resolutions. *Genetic Testing and Molecular Biomarkers*, 25(8), 551–562.

- 7. Xu, L., Earl, J., Bajorski, P., Gonzalez, E., & Pichichero, M. E. (2021). Nasopharyngeal microbiome analyses in otitis-prone and otitis-free children. *International Journal of Pediatric Otorhinolaryngology*, 143, 110629.
- 8. Majer, H. M., Ehrlich, R. L., Ahmed, A., **Earl, J. P.,** Ehrlich, G. D., & Beld, J. (2021). Whole genome sequencing of Streptomyces actuosus ISP-5337, Streptomyces sioyaensis B-5408, and Actinospica acidiphila B-2296 reveals secondary metabolomes with antibiotic potential. *Biotechnology Reports (Amsterdam, Netherlands)*, 29, e00596.
- 9. Nickel*, J. C., Erhlich, G., Doiron, R. C., Kelly, K.-L., & Earl, J. (2020). Mp77-03 the microbiome of Hunner lesions in interstitial cystitis/bladder pain syndrome (ic/bps). *The Journal of Urology*, 203(Supplement 4), e1163–e1164.
- 10. Santos-Cortez, R. L. P., Bhutta, M. F., **Earl, J. P.**, Hafrén, L., Jennings, M., Mell, J. C., Pichichero, M. E., Ryan, A. F., Tateossian, H., & Ehrlich, G. D. (2020). Panel 3: Genomics, precision medicine and targeted therapies. *International Journal of Pediatric Otorhinolaryngology*, 130 Suppl 1, 109835.
- 11. Innamorati, K. A., Earl, J. P., Aggarwal, S. D., Ehrlich, G. D., & Hiller, N. L. (2020). The Bacterial Guide to Designing a Diversified Gene Portfolio. In H. Tettelin & D. Medini (Eds.), *The Pangenome: Diversity, Dynamics and Evolution of Genomes*. Springer.
- 12. Król, J. E., Hall, D. C., Balashov, S., Pastor, S., & Sibert, J. (2019). Genome rearrangements induce biofilm formation in Escherichia coli C–an old model organism with a new application in biofilm research. *BMC Genomics*. https://link.springer.com/article/10.1186/s12864-019-6165-4
- 13. **Earl, J. P.**, Adappa, N. D., Krol, J., Bhat, A. S., Balashov, S., Ehrlich, R. L., ... Mell, J. C. (2018). Species-level bacterial community profiling of the healthy sinonasal microbiome using Pacific Biosciences sequencing of full-length 16S rRNA genes. *Microbiome*, 6(1), 190.
- 14. Greathouse, K. Leigh, James R. White, Ashely J. Vargas, Valery V. Bliskovsky, Jessica A. Beck, Natalia von Muhlinen, Eric C. Polley, Bowman ED, Khan MA, Robles AI, Cooks T, Ryan BM, Padgett N, Dzutsev AH, Trinchieri G, Pineda MA, Bilke S, Meltzer PS, Hokenstad AN, Stickrod TM, Walther-Antonio MR, **Earl JP** et al. 2018. Interaction between the Microbiome and TP53 in Human Lung Cancer. *Genome Biology* 19 (1): 123.
- 15. Earl, J.P., de Vries, S.P.W., Ahmed, A., Powell, E., Schultz, M.P., Hermans, P.W.M., Hill, D.J., Constantinidous, C.I., Hu, F.Z., Bootsma, H.J. and Ehrlich, G.D. Comparative Genomic Analyses of the *Moraxella Catarrhalis* Serosensitive and Seroresistant Lineages Demonstrates Their Independent Evolution. *Genome Biology and Evolution* 8(4)955-974, 2016.
- Rudkjøbing, V.B., Thomsen, T.R., Xu, Y., Melton-Kreft, R., Ahmed, A., Eickhardt-Sørensen, S.R., Bjarnsholt, T., Nielsen, P.H., Earl, J.P., Ehrlich, G.D., and Moser, C. Comparing culture and molecular methods for the identification of microorganisms involved in necrotizing soft tissue infections. *BMC Infectious Diseases* 16:652-664. 2016 DOI 10.1186/s12879-016-1976-2
- 17. Dampier, W., Nonnemacher, M.R., Mell, J.C., **Earl, J.,** Ehrlich, G.D., Pirrone, V., Aiamkitsumrit, B., Zhong, W., Kercher, K., Passic, S., Williams, J.W., Jacobson, J.M., and Wigdahl, B. HIV-1 genetic variation resulting in the development of new quasispecies continues to be encountered in the peripheral blood of well-suppressed patients. *PLoS ONE* 11(5):e015538, 2016.
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- 20. Janto, B., Hiller, N.L., Eutsey, R., Dahlgren, M., Earl, J., Powell, E., Ahmed, A., Hu, F.Z. and Ehrlich, G.D. Development and validation of an *Haemophilus influenzae* supragenome hybridization (SGH) array for transcriptomic analyses. *PLoS One* Oct 7;9(10):e105493. 2014
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 - 23. Janto, B., Ahmed, A., Ito, M., Liu, J., Hicks, D.B., Pagni, S., Fackelmayer, O., Smith, T-A., Earl, J., Elbourne, L., Paulsen, I., Kolstø, A-B., Tourasse, N.J., Ehrlich, G.D., Boissy, R., Ivey, D.M., Li, G., Xue, Y., Ma, Y., Hu, H.Z.,* and Krulwich, T.A.* The genome of alkaliphilic *Bacillus pseudofirmus* OF4 reveals adaptations that support the ability to grow in an external pH range from 7.5 to 11.4 *Environmental Microbiology*. 13(12):3289-3309, 2011
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- 34. Harris, G., and **J. Earl** Perspectives on Pollution and the Basis of Fact: The Case of Environmental Degradation by the Hoosier Magnetics Plant in Ogdensburg, New York. 2006 AJES Vol.13 (No.1).

P. RESEARCH PRESENTATIONS

Rust Belt Microbiome October 2022 Poster <u>Near Full Ribosomal Human-Associated Fungal</u> Microbiome Database

Microbiology Virtual Week Labroots September 2020 Talk <u>Applications of Machine Learning</u> to Predict Clinical Provenance of Haemophilus influenzae

International Lyme and Associated Diseases Society October 2019 Talk <u>Big Data: A Researcher's Perspective</u>

International Society of Otitis Media June 2019 panel session Microbiota: What do we know? Where do we want to go? What is holding us back?

International Society of Otitis Media June 2019 Poster <u>Machine Learning Approaches to Predict *Haemophilus influenzae* Associated Host Disease State, Host Tissue, and Gene "Dark Matter"</u>

Beyond 16S: Strain level microbiome profiling using long read sequencing March 2019 – Talk <u>Pacifying the Peculiar Problem Profile of Pacbio</u>

Sequencing and Finishing Analysis and the Future May 2018 – Talk <u>Predicting Disease and Ecological Niche of Non-Typeable *Haemophilus influenzae* With Machine Learning</u>

Monell Chemical Senses Center Dec 2017 – Talk Oneliner functions in R for Bioinformatics

Evo-Nei Symposium Temple University Sept 2017 – Talk <u>Comparison of Two Machine Learning Techniques to Predict Virulence, And Habitat Of Non-Typeable *Haemophilus Influenzae* Via Gene Possession</u>

ISCB Conference Prague 2017 – Poster <u>Comparison of Two Machine Learning Techniques to</u> Predict Virulence, and Habitat of Non-Typeable *Haemophilus influenzae* Via Gene Possession

Monell Chemical Senses Center 2016 – Talk <u>Creating Functions in R, using R for statistical analysis</u>

International Symposium on Molecular Medicine and Infectious Disease 2016 - Poster presentation Characterization of the Sinonasal Microbiome Using Pacbio Sequencing and MCSMRT

Microbial Population Biology Gordon Conference 2015 – Poster Niche Partitioning of Sino-Nasal Microbiome

Microbiology and Immunology Lab Meeting 2015 – Talk Sino-nasal Microbiome Analysis

Pacific Biosciences User Group Meeting 2015 – Talk <u>Novel 16s Microbiome Analysis Methods</u> <u>Using Pacbio Sequencing</u>

Drexel Discovery Day 2014 – Talk <u>Comparative Genomics Pipeline: *Moraxella catarrhalis* <u>Serumsensitive and Serumresistant Populations</u></u>

American Society for Microbiology 2013 – Poster Whole Genome Comparative Analyses of Multiple Species from the Family Pasteurellaceae

Center for Genomic Sciences 2012 – Talk Bioinformatics at the Center for Genomic Sciences

Horizontal Gene Transfer as a Mechanism of Diversity Generation in *S. pneumoniae*. Polymicrobial Infections and Biofilms in Otitis Media. 10th International Symposium on the Recent Advances in Otitis Media, June 7, 2011, New Orleans, LA. (Plenary Session Talk)

Center for Genomic Sciences 2011 – Talk <u>Using the Program Notung to Identify Putative</u> Genomic Transfers, <u>Duplications</u>, and <u>Losses of Genes</u>

International Society for Computational Biology 2010 – Poster Comparative Genomics of Gardnerella vaginalis using Notung

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 334 of 739 PageID

EXHIBIT 17C

Curriculum Vitae

Name: Dan E. Krane e-mail: Dan.Krane@wright.edu

Address: Department of Biological Phone: (937) 775-2257 (lab)
Sciences (937) 775-3320 (FAX)

Wright State University (937) 426-9270 (office)

Dayton, OH 45435-0001

Educational background:

B.S. (1985) in Biology and Chemistry at John Carroll University, University Heights, OH

Ph.D. (1990) Biochemistry program of the Department of Molecular and Cell Biology, The Pennsylvania State University, University Park, PA

Research interests: Molecular and genome evolution; human population substructuring; forensic DNA profiling; bioinformatics.

Training and positions held:

- **Undergraduate researcher** (1984-1985) Department of Chemistry, John Carroll University
- **Graduate assistant** (1985-1990) Department of Molecular and Cell Biology, The Pennsylvania State University
- Participant (1988) UCLA International School on Molecular Evolution
- **Research Associate** (1990-1991) Howard Ochman and Daniel L. Hartl's laboratory, Department of Genetics, Washington University School of Medicine
- **Research Associate** (1991-1993) Daniel L. Hartl's laboratory, Department of Organismic and Evolutionary Biology, Harvard University
- **Assistant Professor** (1993-2000) Department of Biological Sciences, Wright State University.
- **Affiliate Member of the Biomedical Sciences faculty** (1994-1995) Wright State University.
- **Associate Member of the Biomedical Sciences faculty** (1995-present) Wright State University.
- **Associate Professor** (2000-2007) Department of Biological Sciences, Wright State University.
- **Associate Director, Biomedical Sciences PhD program** (2000-2002) Wright State University.
- University Faculty President (2011-2014, 2019), Wright State University.
- University Faculty Vice President (2017-2019), Wright State University.
- Chair (2012-2019), Ohio Faculty Council.
- **Special Assistant for Completion Initiatives** (2016-2017), Ohio Department of Higher Education.
- **Interim Dean and Chief Administrative Officer** (2019-2022), Wright State University Lake Campus.

Training and positions held (continued):

- President, CEO and Senior Analyst, Forensic Bioinformatics, Inc. (2002-present).
- **Graduate Faculty,** Wright State University Microbiology and Immunology Program (2003-present) Environmental Sciences Ph.D. Program (2003-present).
- Professor (2007-present) Department of Biological Sciences, Wright State University.
- Entrepreneur in Residence (2020-present), Ohio Department of Higher Education.

Awards, honors, and grant support:

- American Institute of Chemists Student Research and Recognition Foundation Award (1985).
- Pella Fay Braucher Scholarship from The Pennsylvania State University College of Science (1985).
- UCLA International School on Molecular Evolution Fellowship (1988).
- The R. Adams Dutcher Fund Award from The Pennsylvania State University Biochemistry Program (1990).
- The W. R. Keck Fellowship from the Washington University School of Medicine (1990).
- Collegium Summer Institute on Faith and Intellectual Life Fellowship (1993).
- Wright State University Alumni Grant for "Computer assisted DNA analysis" for \$2,650 (1993).
- Research Challenge Grant for \$25,000 from Wright State University (1994) for "The influence of regional GC-content on neutral substitutions".
- Finalist, "Teacher of the Year Award," Wright State University, College of Science and Mathematics (1994, 1995, 1997 and 2002).
- The Dean of the College of Science and Mathematics "Special Award for Outstanding Teaching," Wright State University, College of Science and Mathematics (1995).
- Principal investigator: Ohio biological survey for \$500 for "Molecular characterization of Black and Sugar Maples in Ohio." (1995-1996).
- Honorary induction into Alpha Lambda Delta, the National Academic Honor Society for Freshmen (1996).
- "Teacher of the Year Award," Wright State University, College of Science and Mathematics (1997 and 2008).
- Co-investigator (G. Allen Burton, project director): U.S. EPA grant for \$61,814 for "Assessment of sediment quality in the Black River." (1997).
- Co-investigator (G. Allen Burton, project director): U.S. EPA grant for \$449,499 for "Sediment contamination assessment methods: Validation of standardized and novel approaches." (1997).
- Principal investigator: U.S. EPA grant for \$420,277 for "Intraspecies genetic diversity measures of environmental impacts." (1998-2002).
- Principal investigator: Wright State University Early Start/Augmentation grant for \$17,998 for "DNA quantification center for assessing changes in genetic diversity levels" (1999).
- Principal investigator: Ohio biological survey for \$500 for "Survey of the terrestrial isopods of Ohio." (1999-2000).

Awards, honors, and grant support (continued):

- Principal investigator: Ohio biological survey for \$500 for "Survey of the Chironomid species of Ohio." (2001-2002).
- Principal investigator: Various sources of compensation for consulting regarding forensic DNA analyses made payable to Wright State University for approximately \$125,000. (1993-2002).
- Principal investigator: Wright State University Technology Commercialization Initiative Grant for \$99,985 for "Commercialization of DNA profiling expertise." (2001-2002).
- Co-investigator (Mike Raymer, PI): National Science Foundation (Computer Science Directorate) grant for \$542,056 (\$47,254 under the direct control of D. E. Krane) for "Crossing the interdisciplinary barrier: An integrated undergraduate program in bioinformatics." (2001-2005).
- Co-investigator (Keith Grasman, PI): Wright State University College of Science and Mathematics Research Incentive Fund project for \$30,000 for "Environmental health assessments using toxicogenomic technologies." (2001-2003).
- Co-investigator (Gerald Alter, PI): Wright State University College of Science and Mathematics Research Incentive Fund project for \$30,000 for "Establishing an applied biomedical computing center: Using the nucleotide excision repair complex as a paradigm." (2001-2003).
- Co-investigator (with Keith Grasman): Canadian Wildlife Service (Toronto, ON office) for \$5,000 for "The effects of environmental contaminants on sex ratios in young herring gulls in areas of concern." (2001-2002).
 - Participant: State of Ohio Biotechnology Research and Technology
- Transfer grant for \$5.5 million (\$1.9 million to Wright State University; \$600,293 for bioinformatics work) (2002-2005).
- Principal investigator: Wright State University Technology Commercialization Initiative Grant for \$9,007 for "Developing software that generates forensic DNA profiles and meaningful statistics from mixed evidence samples." (2006).
- Co-investigator (with Joe Bartoszek): Systematics Research Fund for \$1,122 for "Phylogeny of hybrid unisexual Ambystomatid salamanders, a new genome." (2008-2009).
- Principal investigator: Research Initiative Grant from Forensic Bioinformatics, Inc. for \$53,338 for "Persistence and Transfer of STR DNA profiles." (2010-2012).
- Principal investigator: Wright State University Teaching Innovation Grant for \$4,270 for "Engaging students in forensic DNA profiling." (2012-2013).
- Omnicron Delta Kappa, Honorious Causa member, Wright State University Circle, National Leadership Honorary Society, 2012.
- Fellow, American Council on Education Leadership Development Program, 2014-2015 cohort; University of Notre Dame, host institution.
- Principal investigator: Executive on-loan grant from the Ohio Department of Higher Education for \$61,500 for "Bridges to Success: Co-requisite remediation for mathematics gateway courses as part of degree pathways." (2016-2017).
- College of Science and Mathematics Outstanding Service Award, Wright State University, 2017.

Awards, honors, and grant support (continued):

Co-investigator (with Jeanna Matthews, Clarkson University; Nathan Adams, Forensic Bioinformatics; Jessica Goldthwaite, New York City Legal Aid; Surya Mattu, Propublica; and David Madigan, Columbia University): Magic Grant for \$50,000. Decoding differences in forensic DNA software. (2018-2019).

Publications:

- Cheng, J.-F., D. E. Krane and R. C. Hardison. 1988. Nucleotide sequence and expression of rabbit globin genes ζ 1, ζ 2, and ζ 3: Pseudogenes generated by block duplications are transcriptionally competent. J. Biol. Chem. **263:**9981-9993.
- Krane, D. E. and R. C. Hardison. 1990. Short interspersed repeats in rabbit DNA can provide functional polyadenylation signals. Mol. Biol. Evol. 7:1-8.
- Krane, D. E. and R. C. Hardison. 1990. Short interspersed repeats in rabbit DNA propagated by successive waves of retrotransposition. Abst. #745, Session 50, ASMBM/AAI 1990 Meeting, FASEB Journal.
- Krane, D. E., A. G. Clark, J.-F. Cheng and R. C. Hardison. 1991. Subfamilies and clustering of C repeats within the rabbit genome. Mol. Biol. Evol. 8:1-30.
- Hardison, R. C., D. E. Krane, D. J. Vandenberg, J.-F. Cheng, J. Mansberger, J. A. Taddie, S. Schwartz, X. Huang, and W. Miller. 1991. Sequence and comparative analysis of the rabbit alpha-like globin gene cluster reveals a rapid mode of evolution in a G+C rich region of mammalian genomes. J. Mol. Biol., 222:233-249.
- Yost, S., M. James-Pederson, J. Xu, D. E. Krane, R. Miller, T. Zeigler and R. C. Hardison. 1991. Intragenic sequences and proteins regulating the rabbit α-globin gene. Pp. 220-234 *in* G. Stamatoyannopoulos and A. W. Nienhuis, eds. The regulation of hemoglobin switching. Johns Hopkins University Press, Baltimore.
- Krane, D. E., D. L. Hartl and H. Ochman. 1991. Rapid determination of nucleotide content and its application to the study of genome structure. Nucl. Acids Res., 19:5181-5185.
- Krane, D. E., R. W. Allen, S. A. Sawyer, D. A. Petrov and D. L. Hartl. 1992. Genetic differences at four DNA typing loci in Finnish, Italian, and mixed Caucasian populations. Proc. Natl. Acad. Sci., USA, **89**:10583-10587.
- Carulli, J. P., D. E. Krane, D. L. Hartl and H. Ochman. 1993. Compositional heterogeneity and patterns of molecular evolution in the *Drosophila* genome. Genetics, **134:**837-845.
- Ostrowski, R. and D. E. Krane. 1993. Unresolved issues in the forensic use of DNA profiling. Accountability in Res., **3:**47-54.

- Ayala, F. J., D. E. Krane and D. L. Hartl. 1994. Genetic variation in IncI1-Collb plasmids. J. Mol. Evol., **39:**129-133.
- DeVere, G. A., J. L. Uy, C. R. Eagler and D. E. Krane. 1995. The function and evolution of rabbit C repeats. Proc. Nat. Conf. Und. Res., **IX:**938-942.
- Sawyer, S., A. Podleski, D. Krane and D. Hartl. 1996. DNA fingerprinting loci do show population differences. Am. J. Hum. Genet., **59:**272-274.
- Skepner, A. P. and D. E. Krane. 1997. cpDNA of *Acer saccharum* and *Acer nigrum* are very similar. OH J. Sci., **97**:90-94.
- York, A. J. and D. E. Krane. 1997. Isochore-related amino acid substitution biases in chickens and humans. Proc. Nat. Conf. Und. Res., XI:614-618.
- Skepner, A. P. and D. E. Krane. 1998. RAPD reveals genetic similarity of *Acer saccharum* and *Acer nigrum*. Heredity, **80:**422-428.
- Krane, D. E., D. Sternburg and G. A. Burton. 1999. Randomly amplified polymorphic DNA profile-based measures of genetic diversity in crayfish are correlated with environmental impacts. Environ. Toxicol. Chem., **18:**504-508.
- Krane, D. E. 2001 Intraspecies genetic diversity measures of environmental impacts. (Lipnick, R. L., R. P. Mason, M. L. Phillips and C. U. Pittman, Eds.) in Chemicals in the environment, American Chemical Society Symposium Series (806) pp. 340-249.
- Newburn, E. and D. E. Krane. 2001. Molecular Identification of Chironomid species. (Lipnick, R. L., R. P. Mason, M. L. Phillips and C. U. Pittman, Eds.) in Chemicals in the environment, American Chemical Society Symposium Series (806) pp. 363-383.
- Pilgrim, E. M., S. A. Roush and D. E. Krane. 2002. Combining DNA sequences and morphology in systematics: testing the validity of the dragonfly species *Cordulegaster bilineata*. Heredity **89:**184-190.
- Doom, T. M. Raymer, D. Krane and O. Garcia. 2003. Crossing the interdisciplinary barrier: A baccalaureate computer science option in bioinformatics. IEEE Transactions on Education **46:**387-393.
- Krane, D. E., M. L. Raymer, and T. E. Doom. 2003. An interdisciplinary bioinformatics program. The Journal of College Science Teaching **XXXII**:296
- Thompson, W. C., S. Ford, T. Doom, M. L. Raymer, and D. E. Krane. 2003. Evaluating forensic DNA evidence: Essential elements in a competent defense review. The Champion **XXVII**: April, 2003:16-25 (Cover story); and May, 2003: 24-28.
- Krane, D. E. and W. C. Thompson. 2003. DNA in the courtroom. Psychological and Scientific Evidence in Criminal Trials, Chapter 11 (144 pages), edited by Jane Campbell Moriarty, West, Danvers, MA.

- Gilder, J. R., S. Ford, T. E. Doom, M. L. Raymer, and D. E. Krane. 2004. Systematic differences in electropherogram peak heights reported by different versions of the GeneScan software. Journal of Forensic Sciences, **49:**92-95.
- Doom, T., M. Raymer, and D. Krane. 2004. Bioinformatics: Where biology meets computer science. IEEE Potentials **23:**24-28.
- Krane, D. E., T. E. Doom, L. D. Mueller, M. L. Raymer, W. M. Shields and W. C. Thompson. 2004. Commentary on "CODIS STR loci data from 41 sample populations." Journal of Forensic Sciences, **49**:1388-1389.
- Paoletti, D. R., T. E. Doom, C. M. Krane, M. L. Raymer and D. E. Krane. 2005. Empirical analysis of the STR profiles resulting from conceptual mixtures. Journal of Forensic Sciences, **50**:1361-1366.
- Paoletti, D. R., T. E. Doom, M. L. Raymer and D. E. Krane. 2006. Assessing the implications for close relatives in the event of similar but non-matching DNA profiles. Jurimetrics. **46:**161-175.
- Heizer, E. M., D. W. Raiford, M. L. Raymer, T. E. Doom, R. V. Miller and D. E. Krane. 2006. Amino acid cost and codon usage biases in six prokaryotic genomes: A whole genome analysis. Molecular Biology and Evolution, 23:1670-1680.
- Rowland, C. D., R. V. Van Trees, M. S. Taylor, M. L. Raymer and D. E. Krane. 2006. Was the Shawnee war chief Blue Jacket a Caucasian? The Ohio Journal of Science **106**(4):126-129.
- Gilder, J. R., T. E. Doom, K. Inman and D. E. Krane. 2007. Run-specific limits of detection and quantitation for STR-based DNA testing. Journal of Forensic Sciences, **52**(1):97-101.
- Krane, D. E., S. Ford, J. R. Gilder, K. Inman, A. Jamieson, R. Koppl, I. L. Kornfield, D. M. Risinger, N. Rudin, M. S. Taylor, W. C. Thompson. 2008. Sequential unmasking: A means of minimizing observer effects in forensic DNA interpretation. Journal of Forensic Sciences, 53(4):1006-1007.
- Krane, D., J. Gilder, R. Koppl, I. Kornfield, L. Mueller and W. C. Thompson. 2008. Comment on the review of low copy number testing. International Journal of Legal Medicine, **123**(6):535-536.
- Raiford, D. W., E. M. Heizer, Miller, R. V., Akashi, H., Raymer, M. L. and D. E. Krane. 2008 Do amino acid biosynthesis costs constrain protein evolution in *Saccharomyces cerevisiae*? Journal of Molecular Evolution, **67**:621-630, 2008.
- Krane, D. E. Allelic Attribution, in Wiley Encyclopedia of Forensic Science (A. Jamieson & Moenssens eds.). 2009.
- Krane, D. E. Low amounts of DNA, in Wiley Encyclopedia of Forensic Science (A. Jamieson & Moenssens eds.). 2009.
- Gilder, J., Koppl, I. Kornfield, D. Krane, L. Mueller, W.C. Thompson. 2009. Comments on the review of low copy number testing. International Journal of Legal Medicine. **123**(6):535-536.

- Krane, D. E., S. Ford, J. R. Gilder, K. Inman, A. Jamieson, R. Koppl, I. L. Kornfield,
 D. M. Risinger, N. Rudin, M. S. Taylor, W. C. Thompson. 2009. Comments on sequential unmasking: A means of minimizing observer effects in forensic DNA interpretation. Journal of Forensic Sciences, 54(2):501.
- Krane, D. E., S. Ford, J. R. Gilder, K. Inman, A. Jamieson, R. Koppl, I. L. Kornfield, D. M. Risinger, N. Rudin, M. S. Taylor, W. C. Thompson. 2009. Comments on sequential unmasking: A means of minimizing observer effects in forensic DNA interpretation. Journal of Forensic Sciences, 54(6):1500-1501.
- Krane, D. E., V. Bahn, D. Balding, B. Barlow, H. Cash, B.L. Desportes, P. D'Eustachio, K. Devlin, T. E. Doom, I. Dror, S. Ford, C. Funk, J. Gilder, G. Hampikian, K. Inman, A. Jamieson, P. E. Kent, R. Koppl, I. Kornfield, S. Krimsky, J. Mnookin, L. Mueller, E. Murphy, D. R. Paoletti, D.A. Petrov, M. Raymer, D. M. Risinger, A. Roth, N. Rudin, W. Shields, J.A. Siegel, M. Slatkin, Y. S. Song, T. Speed, C. Spiegelman, P. Sullivan, A. R. Swienton, T. Tarpey, W. C. Thompson, E. Ungvarsky, S. Zabell. 2009. Time for DNA disclosure. Science. 326:1631-1632.
- Krane, D., S. Ford, J. Gilder, K. Inman, A. Jamieson, R. Koppl, I. Kornfield, D.M. Risinger, N. Rudin, M. Taylor, W.C. Thompson. 2010. Commentary on: "A perspective on errors, bias, and interpretation in the forensic sciences and direction for continuing advancement." Journal of Forensic Sciences. 55(1):273-274.
- Raiford, D. W., D. E. Krane, T. E. Doom and M. L. Raymer. 2010. Automated isolation of translational efficiency bias that resists the confounding effect of GC(AT)-content. IEEE/ACM Transactions on Computational Biology and Bioinformatics, 7(2):238-250.
- Thompson, W., Ford, S., Gilder, J., Inman, K., Jamieson, A., Koppl, R., Kornfield, I., Krane, D., Mnookin, J., Risinger, D., Rudin, N., Saks, M., and S. Zabell. 2010 A reply to Thornton's "A rejection of 'working blind' as a cure for contextual bias." Journal of Forensic Sciences, 55(6): 1663.
- Gilder, J. R., K. Inman, W. Shields and D. E. Krane. 2011. Magnitude dependent variation in peak height balance at heterozygous STR loci. International Journal of Legal Medicine, 125(1): 87-94.
- Raiford, D. W., D. E. Krane, T. E. Doom and M. L. Raymer. 2011. A genetic optimization approach for isolating translational efficiency bias. IEEE/ACM Transactions on Bioinformatics and Computational Biology (TCBB), 8:342-352.
- Heizer, E. M., Raymer, M. L., and D. E. Krane. 2011. Amino acid biosynthetic cost and protein conservation. Journal of Molecular Evolution, **72**(5-6): 466-473.
- Paoletti, D. R., D. E. Krane, M. L. Raymer, and T. E. Doom. 2012. Inferring the number of contributors to mixed DNA profiles. IEEE/ACM Transactions on Computational Biology and Bioinformatics, 9(1): 113-122.
- Raiford, D. W., E. M. Heizer, R. V. Miller, T. E. Doom, M. L. Raymer, and D. E. Krane. 2012. Metabolic and translational efficiency in microbial organisms. Journal of Molecular Evolution, **74**(3-4): 206-216.
- Thompson, W. C., L. D. Mueller, and D. E. Krane. 2012. Forensic DNA statistics: Still controversial in some cases. The Champion, 2012 **13**(9): 14-23.

- Ferguson, C. D., M. J. Blum and M. L. Raymer, M. S. Eackles, and D. E. Krane. 2013. Population structure, multiple paternity, and long-distance transport of spermatozoa in the freshwater mussel *Lampsilis cardium* (Bivalvia: Unionidae). Freshwater Science, **32**(1): 267-282.
- Koppl, R., Charlton, D., Kornfield, I., Krane, D., Risinger, M., Saks, M. and Thompson, W. 2015. Do observer effects matter? Forensic Science Policy & Management: An International Journal, **6:**1-2.
- Dror, I. E., Thompson, W. C., Meissner, C. A., Kornfield, I., Krane, D., Saks, M., and Risinger, M. 2015. Context management toolbox: A linear sequential unmasking (LSU) approach for minimizing cognitive bias in forensic decision making. *J. Forensic Sciences*, **60**:1111-1112.
- Krane, D. E. 2015. Time for DNA database disclosure. *J. Forensic Sciences*, **60:**1668.
- Krane, D. "DNA Mixture Interpretation." In *A Guide to Forensic DNA Profiling*, (Allan Jamieson and Scott Bader eds.) published by JW Wiley. Pages 129-136. March, 2016.
- Krane, D. E. and Ford, S. "Essential Elements of a Critical Review of DNA Evidence." In *Forensic Science Reform*, (Wendy Koen and C. Michael Bowers eds.) published by JW Wiley. Pages 211-238. January, 2017.
- Adams, N., Koppl, R., Krane, D., Thompson, W., and Zabell, S. 2018. Appropriate Standards for Verification and Validation of Probabilistic Genotyping Systems. *J. Forensic Sciences*, **63:**339-340.
- S. Ford and D. Krane. 2018. The dawning of a new era in DNA profiling. *The Champion*, **5**:40-49.
- J. Matthews, M. Babaeianjelodar, S. Lorenz, A. Matthews, M. Njie, N. Adams, D. Krane, J. Goldthwaite, C. Hughes. "The Right to Confront Your Accusers: Opening the Black Box of Forensic DNA Software," In Proceedings of the 2019 AAAI/ACM Conference on AI, Ethics, and Society (AIES). Association for Computing Machinery, New York, NY 321-327.

Published textbooks/manuals:

- Krane, D. E. 1996. A laboratory perspective for introductory biology, 8th edition (128 pages). Van-Griner Publishing, Minster, OH (ISBN 978-1-61740-375-0).
- Krane, D. E. 1996-2019. Cells, genes and genetics lecture notes. (183 pages, soft cover). Wright State University in house publication.
- Krane, D. E. 1996-2013. Molecular genetics lecture notes. (215 pages, soft cover). Wright State University in house publication.
- Krane, D. E. 1998. A laboratory perspective for introductory biology; 2nd edition. (108 pages, hard cover). Simon and Schuster, Needham, MA (ISBN 0-536-01555-4).
- Krane, D. E. 2001. "Molecular Evolution." Chapter 24 of the fifth edition of Peter Russell's *Genetics*, published by Benjamin/Cummings. 49 pages with nine illustrations.

Published textbooks/manuals (continued):

- Krane, D. E. and M. L. Raymer. 2003. *Fundamental Concepts of Bioinformatics*. (A 314-page sophomore/junior level textbook for biology and computer science majors; ISBN 0-8053-4633-3) Pearson Education, Inc., publishing as Benjamin Cummings, San Francisco, CA. (International edition ISBN 0-321-10922-X; Chinese translation ISBN 7-302-09430-6/Q).
- Krane, D. E. 2006. "Molecular Evolution." Chapter 24 of the second edition of Peter Russell's *iGenetics: A Molecular Approach* and second edition of *iGenetics: A Mendelian Approach*, published by Benjamin/Cummings. 52 pages with nine illustrations.

Presentations:

- Cheng, J.-F., D. E. Krane, and R. C. Hardison. July, 1987. The expression and evolution of zeta globin genes. Sixth summer symposium in molecular biology Developmental gene regulation, The Pennsylvania State University, University Park, PA.
- Krane D. E. July, 1988. Subfamily relationships and the structure of rabbit C repeats. UCLA school on molecular evolution, The University of California, Los Angeles.
- Krane D. E., and R. C. Hardison. July, 1989. Rabbit C repeats and their role in the evolution of the rabbit genome. Eighth summer symposium in molecular biology DNA protein interactions, The Pennsylvania State University.
- Krane D. E. April, 1990. The molecular evolution of a short repetitive element in rabbits. Biology departmental seminar, University of Illinois at Champagne-Urbana.
- Krane, D. E. and R. C. Hardison. May, 1990. Short interspersed repeats in rabbit DNA propagated by successive waves of retrotransposition. ASMBM/AAI 1990 Meeting.
- Hardison, R. C., S. E. Yost, M. James-Pederson, D. E. Krane and J. Xu.May, 1990. Intragenic sequences and protein factors regulating expression of the rabbit alpha-globin gene. ASMBM/AAI 1990 Meeting.
- Krane D. E. September, 1990. The rabbit and human alpha and beta globin gene clusters: An empirical analysis of two different isochores. Department of Genetics, Washington University School of Medicine, St. Louis, MO.
- Hardison, R. C., S. E. Yost, M. James-Pederson, D. E. Krane and J. Xu. September, 1990. Intragenic sequences and protein factors regulating expression of the rabbit alpha-globin gene. Seventh Annual Conference on Hemoglobin Switching, Arlie House, VA.
- Krane, D. E. February, 1991. A new method for the analysis of the compartmentalization of vertebrate genomes. Biology and Chemistry Departments, John Carroll University, University Hts., OH.
- Krane, D. E. July, 1991. Analyses of the isochore structure of eukaryotic genomes. St. Louis Red Cross, St. Louis, MO.

- Krane, D. E. June, 1992. DNA profiling and the implications of population substructuring. Merimac Community College summer seminar series for gifted students, St. Louis, MO.
- Krane, D. E. October, 1992. Population genetics and forensic DNA typing.

 North Carolina Biotechnology Center/BASF Corporation Lecture Series in Biotechnology, The University of North Carolina at Charlotte.
- Krane, D. E. December, 1992. DNA profiling: A primer. Special seminar for the Missouri State Trial Lawyers Association, St. Louis, MO.
- Krane, D. E. March, 1993. Unresolved issues in the forensic application of DNA profiling. Department of Biology, Morehead State University, Morehead, KY.
- Krane, D. E. February, 1994. The structure and evolution of warm-blooded vertebrate genomes. Department of Biochemistry and Molecular Biology, Wright State University, Dayton, OH.
- Krane, D. E. April, 1994. A homogenating bias in the accumulation of mutations in primate isochores. Museum of Comparative Zoology, Harvard University, Cambridge, MA.
- Krane, D. E. and D. Barr. May, 1994. Evolutionism vs. Creationism on "Current Perspectives: WAZU (102.9 FM), Dayton, OH.
- Krane, D. E. and R. Keyes. May, 1994. Evolution/Creation Discussion, sponsored by the Wright State University Campus Crusade for Christ, Dayton, OH.
- Krane, D. E., M. Malinowski, E. W. Morgan and B. Gorman. January, 1995. Scientific Evidence on Trial. Wright State Policy Forum, Dayton, OH.
- Krane, D. E. February, 1995. Forensic applications of DNA. The Dayton Sertoma Club, Dayton, OH.
- Krane, D. E. April, 1995. DNA forensics. 1995 Bi-state conference of the Indiana and Ohio Societies for Clinical Laboratory Science, Fairborn, OH.
- Krane, D. E. June, 1995. Computer applications in DNA analyses. 1995 Regional meeting of the Academic Computing Society, Dayton, OH.
- Krane, D. E. December, 1995. Forensics in the '90's. The University of Cincinnati and Benjamin/Cummings. Cincinnati, OH.
- Krane, D. E. February, 1996. Polymorphisms at hypervariable loci and human population substructuring. Heidelberg College, Tiffin, OH.
- Krane, D. E., P. Donnelly and M. Kreitman. February, 1996. An afternoon symposium on the statistical interpretation of DNA evidence. DePaul University, Chicago, IL.
- Krane, D. E. April, 1996. Forensics in the '90's. The University of Massachussets at Worchester and Benjamin/Cummings. Worcester, MA.

- Sternberg, D. V., G. A. Burton, D. E. Krane and K. Grasman. April, 1996.
 Randomly amplified polymorphic DNA markers in determinations of genetic variation in populations affected by stressors. Abstr. Annu. Meet. Soc. Env. Toxicol. Chem., Washington, D.C., p. 259, no. P0882.
- Krane, D. E. May, 1996. DNA profiling: from start to finish. State of Missouri Public Defenders, St. Louis, MO.
- Krane, D. E. January, 1996. Strong base-composition altering mutational biases operating within primate genomes are dependent upon isochore GC-contents. American Society for Human Genetics Meeting, Minneapolis, MN.
- Hostler, D. P. and D. E. Krane. July, 1996. The dependence of rate and mode of evolution on genomic context within primates. Fifteenth summer symposium in molecular biology Genome and chromatin structure, The Pennsylvania State University, University Park, PA.
- Skepner, A. P. and D. E. Krane. July, 1996. The application of random amplification of polymorphic DNA to phylogenetic reconstructions. Fifteenth summer symposium in molecular biology Genome and chromatin structure, The Pennsylvania State University, University Park, PA.
- Steinbrugge, K. and D. E. Krane. July, 1996. A re-analysis of the function and role of SINEs within mammalian genomes. Fifteenth summer symposium in molecular biology Genome and chromatin structure, The Pennsylvania State University, University Park, PA.
- Krane, D. E. October, 1996. Isochore-dependent mutational biases: A new perspective on random genetic drift. The University of Dayton, Dayton, OH.
- Krane, D. E. January, 1997. Minor shifts in genomic GC-content alter amino acid fixational bias. International Society of Molecular Evolution meeting, Guanacaste, Costa Rica.
- Krane, D. E. February, 1997. The potential and pitfalls of DNA profiling. The Harvard Club of Dayton, Dayton, OH.
- Krane, C. M. and D. E. Krane. April, 1997. The potential of molecular genetics. American Association of University Women, Dayton, OH.
- Krane, D. E. April, 1997. Compositional bias of point substitutions and insertion events in *Alu-J* repetitive sequences. The Jacques Monod Institute of Molecular Genetics, Paris, France.
- Krane, D. E. May, 1997. Isochore-dependent mutational biases and the neutral theory of molecular evolution. International Conference on Molecular Biology and Evolution, Munich (Kongresshaus Garmisch-Partenkirchen), Bavaria, Germany.
- Krane, D. E. September, 1997. The influence of genomic context upon neutral substitutions. Wright State University, Department of Biological Sciences, Dayton, OH.
- Krane, D. E. November, 1997. The influence of large-scale genomic context upon neutral substitutions. The University of Cincinnati, Department of Medical Genetics, Cincinnati, OH.

- Krane, D. E. February, 1998. From genes to genomes and beyond: Societal implications of genetics and biotechnology. Xenia Rotary Club, Xenia, OH.
- Krane, D. E. March, 1998. The influence of large-scale genomic context upon amino acid replacements. The Pennsylvania State University, Department of Biology, State College, PA.
- Sternberg, D. V., G. A. Burton, D. E. Krane and K. Grasman. April, 1998.

 Randomly amplified polymorphic DNA markers in determinations of genetic variation in aquatic species affected by stressors. Annu. Meeting Central Great Lakes Regional Chapter Society of Environmental Toxicology and Chemistry. East Lansing, MI.
- York, Allen J. and D. E. Krane. April, 1997. Evolution and function of highly repeated short sequences within the rabbit genome. (OH. J. Sci., 98:7). 107th meeting of the Ohio Academy of Science, Middletown, OH.
- Skepner, Adam P. and D. E. Krane. April, 1997. Molecular analyses reveal genetic similarity of *Acer saccharum* and *Acer nigrum*. (OH. J. Sci., 98:14). 107th meeting of the Ohio Academy of Science, Middletown, OH.
- Krane, D. E. April, 1997. Genetic diversity provides a useful measure of environmental impacts. (OH. J. Sci., 98:7). 107th meeting of the Ohio Academy of Science, Middletown, OH.
- Krane, D. E. October, 1998. The influence of large-scale genomic context upon neutral nucleotide substitutions. The University of Cincinnati, Department of Biology, Cincinnati, OH.
- Krane, D. E. April, 1999. DNA profiling as a means of assessing environmental impacts. John Carroll University, Department of Chemistry, University Heights, OH.
- Krane, D. E. October, 1999. The potential and pitfalls of forensic DNA profiling. Wilberforce University, Natural Sciences Division, Wilberforce, OH.
- Grunwald, B., S. A. Roush, and D. E. Krane. November, 1999. Genetic diversity measures of terrestrial isopods as ecoindicators. Society of Environmental Toxicology and Chemistry 20th annual meeting, Philadelphia, PA.
- Krane, D. E., D. C. Sternberg, B. Grunwald, S. A. Roush, and G. A. Burton. November, 1999. RAPD DNA profile-based measures of genetic diversity are correlated with environmental impacts. Society of Environmental Toxicology and Chemistry 20th annual meeting, Philadelphia, PA.
- Krane, D. E. March, 2000. Examiner bias in laboratory analyses of forensic DNA evidence. Miscarriages of Justice conference (co-hosted by the University of California at Irvine and the California Public Defenders' Association), Newport Beach, CA.

- Krane, D. E. May, 2000. Genetic diversity measures of environmental impacts. 2000 STAR Ecosystem Indicators Progress Review Workshop, Las Vegas, NV.
- Krane, D. E. May, 2000. Effects of stressors on genetic diversity in naturally occurring populations, Ohio Valley Chapter of SETAC, 17th annual meeting, College Corner, OH.
- Newburn, E. and D. E. Krane. August, 2000. Molecular Identification Markers of Chironomid Species for Use as an Ecoindicator of Aquatic Systems, Poster and abstract, American Chemical Society National Meeting, Washington D.C.
- Ott, L. and D. E. Krane. August, 2000. Genetic diversity in Pacific herring populations, Poster and abstract, American Chemical Society National Meeting, Washington D.C.
- Krane, D. E. October, 2000. Three generations of DNA profiling: What problems still remain? Eastern Kentucky University, Richmond, KY.
- Newburn, E. and D. E. Krane. November, 2000. Molecular Identification Markers of Chironomid Species for Use as an Ecoindicator of Aquatic Systems, Poster and abstract, 20th Annual SETAC National Meeting, Nashville, TN.
- Ott, L. and D. E. Krane. November, 2000. Genetic diversity in Pacific herring populations, Poster and abstract, 20th Annual SETAC National Meeting, Nashville, TN.
- Krane, D. E. and B. Grunwald, Jr. November, 2000. Genetic diversity as an ecoindicator, Invited presentation, 20th Annual SETAC National Meeting, Nashville, TN.
- Krane, D. E. December, 2000. Correlations between genetic diversity and exposure to stress, Biology Departmental Seminar, Akron University, Akron, OH.
- Krane, D. E. January, 2001. Business opportunities in the area of DNA consulting. Information Technology Research Initiative, Executive Board Meeting, Wright State University, Dayton, OH.
- Newburn, E. and D. E. Krane. March, 2001. Molecular Identification Markers of Chironomid Species for Use as an Ecoindicator of Aquatic Systems, Poster and abstract, MEEC Conference, Oxford, OH.
- Jastremski, K. and D. E. Krane. March, 2001. Genetic diversity in pill bugs at remediated and unremediated strip mines throughout Ohio, Poster and abstract, MEEC Conference, Oxford, OH.
- Walker, S., J. Amon, and D. E. Krane. April, 2001. A genetic comparison of *Lythrum salicaria* and *Lythrum vigratum*. Ohio Academy of Sciences 111th meeting, Tippin, OH.
- Schmidt, S., D. Cipollini, and D. E. Krane. April, 2001. RAPD-PCR assessment of the genetic diversity within *Alliaria petiolata*. Ohio Academy of Sciences 111 th meeting, Tippin, OH.

- Burton, G. A., M. Morris, D. E. Krane, K. Grasman, W. Carmichael, S. Berberich, D. Organisciak and J. Lucot. April, 2001. Human and environmental risk assessment related research at Wright State University. EPA/DOD special conference on toxicology, Dayton, OH.
- Krane, D. E. May, 2001. Hallmarks of research and forensic science. Third annual DePaul University Law School and Cook County Public Defenders' short course on DNA analysis, Chicago, IL.
- Krane, D. E. August, 2001. Genomes as information storage systems. Summer Institute on Advanced Computation, Wright State University, Dayton, OH.
- Krane, D. E. September 2001. Genetic diversity of naturally occurring populations as an ecoindicator. Biology Departmental Seminar, Northern Kentucky University, Highland Heights, KY.
- Krane, D. E. September, 2001. The potential and pitfalls of forensic DNA profiling. Sigma Xi Distinguished Lecturer Series, Northern Kentucky University, Highland Heights, KY.
- Krane, D. E. September, 2001. The science behind forensic DNA profiling. Engineer's Club of Dayton Sertoma lecture series, Dayton, OH.
- Doom, T, M. Raymer, D. Krane and O. Garcia. February, 2002. A proposed undergraduate bioinformatics curriculum for computer scientists. Proceedings of the 2002 ACM Special Interest Group on Computer Science Education (SIGCSE 2002), Covington, KY.
- Krane, D. E. May, 2002. Genophiler: Advantages of automated review of forensic DNA evidence. Fourth annual DePaul University Law School and Cook County Public Defenders' short course on DNA analysis, Chicago, IL.
- Krane, D. E. June, 2002. Reaching out to computer science and biology majors interested in bioinformatics at the same time. Introducing Bioinformatics to Undergraduate Curricula Conference, hosted by Wheaton College, Norton, MA.
- Krane, D. E. March, 2003. Commercialization: Why do it? Ohio Valley Affiliates for Life Sciences, Kingsgate Conference Center, Cincinnati, OH.
- Gilder, J. R., D. E. Krane, T. E. Doom and M. L Raymer. April, 2003. Identifying patterns in DNA change. Proceedings of the 2003 Midwest Artificial Intelligence and Cognitive Science Conference (MAICS 2003: **34**, 78-84). Cincinnati, OH.
- Gilder, J., S. Ford, M. Raymer, T. Doom and D. Krane. September, 2003. Differences in electropherogram peak heights reported by different versions of the GeneScan software. Promega Meeting, Phoenix, AZ.
- Raymer, M. L., T. E. Doom and D. E. Krane. September, 2003. Bioinformatics: Crossing the interdisciplinary boundary. NSF grantees meeting, Washington, DC.
- Krane, D. E. October, 2003. Evaluating forensic DNA evidence. Indiana State Investigators Meeting, Indianapolis, IN.
- Krane, D. E. October, 2003. Bioinformatics education: Crossing the interdisciplinary boundary. Keynote address; Bio21: Teaching Biology with Bioinformatics, Chapel Hill, NC.

- Krane, D. E. November, 2003. Evaluating forensic DNA evidence. Virginia State Bar Association Capital Litigation Meeting, Richmond, VA.
- Krane, D. E. December, 2003. Evaluating forensic DNA evidence. Indiana Public Defender's Capital Litigation Meeting, Indianapolis, IN.
- Krane, D., M. Raymer and T. Doom. March, 2004. Bioinformatics at Wright State University. Ohio Valley Affiliates for Life Sciences, University of Louisville, Louisville, KY.
- Converse, K. and D. Krane. March, 2004. Forensic DNA testing and review. "Life in the Balance" conference and annual meeting of the National Association of Criminal Defense Lawyers, Memphis, TN.
- Krane, D. E. March, 2004. Evaluating forensic DNA evidence. Featured address for "Life in the Balance" conference and annual meeting of the National Association of Criminal Defense Lawyers, Memphis, TN.
- Krane, D. E. April, 2004. Evaluating forensic DNA evidence. "Mindful Explorations" seminar series funded by the William H. and Jean R. Reller Endowment, Indiana University East, Richmond, IN.
- Cooper, G., M. Raymer, T. Doom, D. Krane and N. Futamura. May, 2004. Indexing genomic databases. Proceedings of the 2004 IEEE international symposium on Bioinformatics and Bioengineering (BIBE), Taichung (Taiwan), p. 587-591.
- Krane, D. E. October, 2004. Forensic DNA evidence: collection, mixture and degradation. Virginia State Bar Association Capital Litigation Meeting, Richmond, VA.
- Krane, D. E. October, 2004. Evaluating forensic DNA evidence. Mississippi Public Defenders' Capital Litigation Meeting, Biloxi, MS.
- Thompson, W. C. and D. E. Krane. February, 2005. Evaluating forensic DNA evidence. National Association of Criminal Defense Lawyers Annual Meeting, featured presentation, New Orleans, LA.
- Krane, D. E. April, 2005. Evaluating forensic DNA evidence. Cuyahoga County Capital Litigation Seminar, Cleveland, OH.
- Krane, D. E. April, 2005. The strengths and weakness of forensic DNA profiling techniques. Biology departmental seminar, John Carroll University, University Heights, OH.
- Krane, D. E. April, 2005. Deciphering the human genome with bioinformatics techniques. Café Scientifique Seminar Series, Cox Arboretum, Dayton, OH.
- Krane, D. E. May, 2005. Objective interpretation of forensic DNA testing evidence. Seventh annual DePaul University Law School and Cook County Public Defenders' short course on DNA analysis, Chicago, IL.
- Krane, D. E. and W. C. Thompson. July, 2005. Evaluating forensic DNA evidence. North Carolina Academy of Defense Lawyers, Sunset Beach, NC.

- Krane, D. E., T. E. Doom and M. L. Raymer. August, 2005. Assessing the implications for close relatives in the event of similar but non-matching DNA profiles. Fourth annual Expert Forum on the Science of DNA Profiling, University of Dayton School of Law, Dayton, OH.
- Heizer, E. and D. Krane. September, 2005. Correlation between major codon usage and amino acid biosynthetic costs in eight prokaryotic species. Wright State University Biology Department Research Forum, Dayton, OH.
- Sharma, M. and D. Krane. September, 2005. Molecular characterization of Chironomid Species and their use as bioindicators. Wright State University Biology Department Research Forum, Dayton, OH.
- Gilder, J. R. and Krane, D. E. October, 2005. Objective evaluation of DNA evidence. Indiana University East, Richmond, IN.
- Krane, D. E. October, 2005. Evaluating forensic DNA evidence: What software can and cannot do. Illinois Institute for Continuing Legal Education Death Penalty Litigation Seminars, Springfield, IL.
- Rowland, C, R. Van Trees, M. Taylor, and D. Krane. February, 2006. Was the Shawnee war chief Blue Jacket a Caucasian? 58th Annual Meeting of the American Academy of Forensic Sciences, Seattle, WA.
- Krane, D. E. March, 2006. Essential elements of a review of forensic DNA profile evidence. National Legal Aid and Defender Association National Meeting, Philadelphia, PA.
- Krane, D. E. March, 2006. Objective characterization of technical artifacts in forensic DNA profiles. Illinois Institute for Continuing Legal Education Scientific Evidence Seminars, Chicago, IL.
- Rowland, C, R. Van Trees, M. Taylor, and D. Krane. April, 2006. Was the Shawnee war chief Blue Jacket a Caucasian? Annual Meeting of the Ohio Academy of Science, Dayton, OH.
- Gilder, J. R., T. E. Doom, M. L. Raymer, K. Inman, and D. E. Krane. April, 2006. Resolution of forensic DNA mixtures. Annual Meeting of the Ohio Academy of Science, Dayton, OH.
- Krane, D. E. May, 2006. Familial searches and debating the significance of DNA database "cold hits." Illinois Institute for Continuing Legal Education Death Penalty Litigation Seminars, Springfield, IL.
- Krane, D. E. May, 2006. GenoStat®: A user-friendly alternative to PopStats for calculating random match probabilities. Eigth annual DePaul University Law School and Cook County Public Defenders Seminar Series on DNA Analysis, Chicago, IL.
- Raiford, D. W., D. E. Krane, T. E. Doom and M. L. Raymer. July, 2006. An investigation of codon usage bias: Isolation and visualization of translation bias in organisms exhibiting multiple biases. The Ohio Collaborative Conference on Bioinformatics, Athens, OH.

- Krane, D. E., T. E. Doom and M. L. Raymer. August, 2006. Run-specific limits of quantitation and detection (an alternative to minimum peak height thresholds for DNA profile analyses). Fifth annual Expert Forum on the Science of DNA Profiling, Sinclair Center, Dayton, OH.
- Krane, D. E. September, 2006. Evaluating forensic DNA evidence. Wright State University Department of Biological Sciences departmental seminar, Dayton, OH.
- Krane, D. E. and R. Cassanova. September, 2006. Evaluating forensic DNA evidence. Indiana Public Defender's Capital Litigation Meeting, Indianapolis, IN.
- Raiford, D. W., D. E. Krane, T. E. Doom, and M. L. Raymer. October, 2006. Isolation and visualization of codon usage biases. Proceedings of the 6th IEEE Symposium on Bioinformatics and Bioengineering (BIBE 2006), Washington, DC.
- Krane, D. E. October, 2006. Evaluating forensic DNA evidence. Illinois Continuing Legal Education (ICLE) program, Springfield, IL.
- Krane, D. E. December, 2006. Amino acid cost and codon usage biases in six prokaryotic genomes: A whole genome analysis. Oklahoma State University Microbiology Department Seminar, Stillwater, OK.
- Krane, D. E. February, 2007. Run-specific limits of quantitation and detection (an alternative to minimum peak height thresholds). American Academy of Forensic Sciences (AAFS) 59th annual meeting, San Antonio, TX.
- Krane, D. E. and J. R. Gilder. November, 2006. Essential elements of a defense review of DNA testing results. Midwestern Academy of Forensic Sciences (MAFS) annual meeting, Indianapolis, IN.
- Krane, D. E. January, 2007. Evaluating forensic DNA evidence. National Association of Criminal Defense Lawyers Annual Meeting, New Orleans, LA.
- Krane, D. E. February, 2007. Assessing the implications for close relatives in the event of similar but non-matching DNA profiles. American Academy of Forensic Sciences (AAFS) 59th annual meeting, San Antonio, TX.
- Krane, D. E. February, 2007. Empirical analysis of the STR profiles resulting from conceptual mixtures. American Academy of Forensic Sciences (AAFS) 59th annual meeting, San Antonio, TX.
- Krane, D. E. March, 2007. Some of the problems associated with LCN (Low Copy Number) DNA testing. The Forensic Institute 2007 Forensic e-Symposium on Human Identification: Profiling of degraded and low amounts of DNA.
- Krane, D. E. March, 2007. The statistics of DNA profiling a day long workshop. The Washington, DC Public Defenders' Office, Washington, DC.
- Krane, D. E., J. R. Gilder, E. Ungvarsky, and A. Jamieson. May, 2007. Essential elements of a defense review of DNA testing results. Mid-Atlantic Academy of Forensic Sciences (MAAFS) annual meeting, Washington, DC.

- Krane, D. E., T. E. Doom and M. L. Raymer. August, 2007. Run-specific limits of quantitation and detection: an alternative to minimum peak height thresholds for DNA profile analyses. Sixth annual Expert Forum on the Science of DNA Profiling, Sinclair Center, Dayton, OH.
- Krane, D. E., T. E. Doom and M. L. Raymer. August, 2007. Familial searches and cold hit statistics. Sixth annual Expert Forum on the Science of DNA Profiling, Sinclair Center, Dayton, OH.
- Raiford, D. W., D. E. Krane, T. E. Doom, and M. L. Raymer. October, 2007. A multi-objective genetic algorithm that employs a hybrid approach for isolating codon usage bias indicative of translational efficiency. Proceedings of the 7th IEEE Symposium on Bioinformatics and Bioengineering (BIBE 2007), volume 1, pages 278-285, Cambridge, MA.
- Krane, D. E. and W. C. Thompson. October, 2007. Evaluating forensic DNA evidence a day-long workshop. Northern Ireland Criminal Bar Association, Belfast, Northern Ireland.
- Krane, D. E. and Angel Carracedo. December, 2007. Forensic DNA profiling a two day-long workshop. Chilean Department of Forensic Sciences, Santiago, Chile.
- Krane, D. E. April, 2008. Expert witnesses: What are they thinking? Mad Anthony Writers' Convention, Hamilton, OH.
- Krane, D. E. May, 2008. Familial searching in policy and practice. Science in the Courtroom for the 21st Century: Issues in Forensic DNA, DePaul Center for Science and the Cook County Public Defender, Chicago, IL.
- Krane, D. E. May, 2008. Y-STR testing validation and the Virginia example. Science in the Courtroom for the 21st Century: Issues in Forensic DNA, DePaul Center for Science and the Cook County Public Defender, Chicago, IL.
- Krane, D. E. May, 2008. The science and pseudoscience of DNA profiling. Cuyahoga County Bar Association, Cleveland, OH.
- Krane, D. E. September, 2008. Emerging issues in forensic DNA profiling: databases and advisory boards. National Center for State Legislatures Annual Meeting, Columbus, OH.
- Krane, D. January, 2009. Evaluating forensic DNA evidence. Fifth National Seminar on Forensic Evidence and the Criminal Law, Philadelphia, PA.
- Krane, D. E., S. Ford, J. R. Gilder, K. Inman, A. Jamieson, R. Koppl, I. L. Kornfield, D. M. Risinger, N. Rudin, M. S. Taylor, W. C. Thompson. February 2009. Sequential unmasking: Determining what information is crucial and what is extraneous in a forensic analysis. American Academy of Forensic Sciences (AAFS) 61st annual meeting, Denver, CO.
- Krane, D. May, 2009. Evaluating forensic DNA evidence. Virginia Public Defenders' continuing education seminar series, Richmond, VA.

- Krane, D. and J. Gilder. June, 2009. Evaluating forensic DNA evidence. The Netherlands Bar Association and Leiden University Law School, The Netherlands.
- Gilder, J. and D. Krane. May, 2009. Searching for (and finding) relatives in forensic DNA databases. Eleventh annual DePaul University Law School and Cook County Public Defenders' short course on DNA analysis, Chicago, IL.
- Gilder, J. and D. Krane. May, 2009. SWGDAM recommendations regarding familial searches. Eleventh annual DePaul University Law School and Cook County Public Defenders' short course on DNA analysis, Chicago, IL.
- Krane, D. and J. Gilder. May, 2009. New developments in DNA technology and litigation. Eleventh annual DePaul University Law School and Cook County Public Defenders' short course on DNA analysis, Chicago, IL.
- Krane, D. July, 2009. Evaluating forensic DNA evidence. National Association of Death Penalty Litigators annual meeting, Airlie, VA.
- Krane, D. November, 2009. Evaluating forensic DNA evidence. Ohio Academy of Criminal Defense Lawyers Death Penalty Seminars, Columbus, OH.
- Krane, D. January, 2010. The science (and pseudoscience) of forensic DNA profiling. Pub-Science series, sponsored by the Boonshoft Museum of Discovery, Dayton, OH.
- Rowland, C. and D. Krane. February, 2010. The National Academy of Sciences report and the Law Commission Consultation paper: Differences and similarities between the United States and England and Wales. The American Academy of Forensic Sciences 63rd Annual Scientific Meeting, Seattle, WA.
- Gilder, J. and D. Krane. February, 2010. Examining of the case of the Deventer murder in the Netherlands. The American Academy of Forensic Sciences 63rd Annual Scientific Meeting, Seattle, WA.
- Gilder, J. and D. Krane. February, 2010. Beer, Wine, and Forensic Science. The American Academy of Forensic Sciences 63rd Annual Scientific Meeting, Seattle, WA.
- Gilder, J. and D. Krane. February, 2010. Discovering relatives in STR DNA databases. The American Academy of Forensic Sciences 63rd Annual Scientific Meeting, Seattle, WA.
- Krane, D. March, 2010. Low copy number (LCN) DNA profiling. The Innocence Project, Cardozo Law School, New York, NY.
- Krane, D. April, 2010. Evaluating forensic DNA evidence. Steelman Visiting Scientist Lecture Series, Lenoir-Rhyne University, Hickory, NC.
- Krane, D. April, 2010. Establishing parameters for objective interpretation of DNA profile evidence. Steelman Visiting Scientist Lecture Series, Lenoir-Rhyne University, Hickory, NC.
- Krane, D. May, 2010. Low Copy Number DNA Testing and New developments in DNA technology. Twelfth annual DePaul University Law School and Cook County Public Defenders' short course on DNA analysis, Chicago, IL.

- Krane, D. and K. Inman. August, 2010. The science (and pseudoscience) of forensic DNA profiling. A day-long workshop held for an international audience in St. Croix, The United States Virgin Islands.
- Krane, D. September, 2010. Forensic DNA profiling at the 2010 Annual Meeting of the Ohio Judicial Conference: The intersection of law, science and ethics. September, 2010, Dublin, OH.
- Krane, D. September, 2010. The science (and pseudoscience) of forensic DNA profiling. A day-long workshop sponsored by the Office of the Attorney General, St. Thomas, The United States Virgin Islands.
- Krane, D. November, 2010. Low copy number (LCN) DNA profiling. Promega Meeting on Human Identification, San Antonio, TX.
- Krane, D. April, 2011. Forensic DNA profiling: interpretation, statistics and challenges (a series of three presentations), New York City DNA College, New York, NY.
- Krane, D. May, 2011. Suspect-centric combined probabilities of inclusion. Thirteenth annual Cook County Public Defenders' short course on DNA analysis, Chicago, IL.
- Krane, D. October, 2011. Forensic DNA profiling and the use of Y-STRs in casework. Mississippi Public Defender Conference, Choctaw, MS.
- Krane, D. November, 2011. Forensic DNA profiling. Federal Bar Council, Mohonk Mountain House, New Paltz, NY.
- Krane, D. November, 2012. Attaching weight to DNA profiles. Doughty Street Chambers, London, England.
- Krane, D. November, 2012. Evaluating Forensic DNA profiling. Missouri Bar Fall Continuing Legal Education Workshop, Kansas City, MO.
- Krane, D. December, 2012. DNA technology in court. Forensic DNA Profiling Video Series, http://youtu.be/Xz3mQS5WwlM.
- Krane, D. December, 2012. Generating forensic DNA profiles. Forensic DNA Profiling Video Series, http://youtu.be/iksXzsL2Y21.
- Krane, D. December, 2012. Statistical weight of single source DNA profiles. Forensic DNA Profiling Video Series, http://youtu.be/EVf4HqUI0Hk.
- Krane, D. December, 2012. Statistical weight of mixed DNA profiles. Forensic DNA Profiling Video Series, http://youtu.be/daRBTopFA1A.
- Krane, D. December, 2012. Implications of database searches for DNA profiling statistics. Forensic DNA Profiling Video Series, http://youtu.be/eY4s1cEk-BQ.
- Krane, D. December, 2012. Artifacts and noise in DNA profiling. Forensic DNA Profiling Video Series, http://youtu.be/94NnYCKesQU.
- Krane, D. December, 2012. Observer effects in DNA profiling. Forensic DNA Profiling Video Series, http://youtu.be/XpXxUrhDUi4.
- Krane, D. December, 2012. What can go wrong with DNA profiling. Forensic DNA Profiling Video Series, http://youtu.be/q4ZU6wb76pU.

- Krane, D. March, 2013. Forensic DNA profiling. Take Our Daughters and Sons to Work Day, Wright State University, Dayton, OH.
- Krane, D. May, 2013. Advances in forensic DNA profiling. Fourteenth annual Cook County Public Defenders' short course on DNA analysis, Chicago, IL.
- Krane, D. September, 2013. The science (and pseudoscience) of forensic DNA profiling. Special guest presenter, Writer's Police Academy, Jamestown, NC.
- Krane, D. September, 2013. Statistical weights for mixed DNA profiles. Doughty Street Chambers, London, England.
- Krane, D. September, 2013. Bayesian approaches to weighting DNA profile evidence. Northern Ireland Criminal Bar Association, Belfast, Northern Ireland.
- Krane, D. February, 2014. The time has come to analyze DNA profile databases. Annual meeting of the American Academy of Forensic Sciences, Jurisprudence section platform presentation, Seattle, WA.
- Krane, D. February, 2014. Suspect-Centric Combined Probability of Inclusion: A means of attaching objective statistical weights to mixed DNA profiles where drop out may have occurred. Annual meeting of the American Academy of Forensic Sciences, Criminalistics section platform presentation, Seattle, WA.
- Houston, E., and D. Krane. February, 2014. Effect of machine laundering additives on human blood. Annual meeting of the American Academy of Forensic Sciences, Poster presentation, Seattle, WA.
- Krane, D. April, 2014. Forensic DNA profiling. Take Our Daughters to Work Day, Wright State University, Dayton, OH.
- Krane, D. May, 2014. The science (and pseudoscience) of forensic DNA profiling. Biology Departmental Seminar, Youngstown State University, Youngstown, OH.
- Krane, D. May, 2014. Attaching statistical weights to mixed DNA profiles where drop out may have occurred. Fifteenth annual Cook County Public Defenders' forensics forum, hosted by DePaul University, Chicago, IL.
- Krane, D. May, 2014. The implications of database analyses to CODIS searches. Fifteenth annual Cook County Public Defenders' forensics forum, hosted by DePaul University, Chicago, IL.
- Krane, D. June, 2014. Attaching statistical weights to DNA profiles. Kingsley Napley Chambers, London, England.
- Krane, D. June, 2014. Statistical weights for low-level mixed DNA profiles. Doughty Street Chambers, London, England.
- Krane, D. June, 2014. Attaching statistical weights to DNA profiles. University College London Crime and Forensic Science distinguished lecturer seminar program, London, England.
- Krane, D. and W. C. Thompson. June 2014. Complex, mixed DNA profiles. The National Innocence Project's DNA College, hosted by Yeshiva University, New York, NY.

- Krane, D. and W. C. Thompson. June 2014. Low copy number DNA profiling. The National Innocence Project's DNA College, hosted by Yeshiva University, New York, NY.
- Krane, D. June 2014. Software approaches for attaching statistical weights to complex mixed DNA profiles. The National Innocence Project's DNA College, hosted by Yeshiva University, New York, NY.
- Krane, D. January, 2015. The science (and pseudoscience) of forensic DNA profiling. Montgomery County Library seminar series, Kettering, OH.
- Krane, D. September, 2014. Exploring bias in forensic DNA profiling. TEDxDayton, Dayton, OH.
- Krane, D. January, 2015. The science (and pseudoscience) of forensic DNA profiling. Biology Departmental Seminar, University of Notre Dame, Notre Dame, IN.
- S. Al-Awadi, M. Sabbaha, N. Adams, A. Marshall, C. Rowland and D. Krane. February, 2015. Pairwise Comparisons as a Means of Validating Iraqi Muslim and Christian Allele Frequency Databases (poster). 67th Annual Meeting of the American Academy of Forensic Sciences. Orlando, FL.
- Coble, M. D. and D. Krane. April, 2015. Low-level DNA mixtures and interpretation. Science, cell phones and social media Finding & using evidence in post-conviction cases. National Association of Criminal Defense Lawyers in collaboration with the Innocence Network, Orlando, FL.
- Krane, D. May, 2015. Sequential unmasking: A means of minimizing observer effects in forensic interpretation. Forensic bias and error Causes and corrections. Sixteenth annual Cook County Public Defenders' forensics forum, hosted by John Marshall Law School, Chicago, IL.
- R. Koppl, D. Krane, N. Adams. July, 2015. Minimizing and leveraging bias in forensic science. National Institute of Standards and Technology International Symposium on Forensic Science Error Management. Washington, DC.
- Krane, D. and K. Inman. October, 2015. Probabilistic genotyping in forensic DNA profiling. DNA Bootcamp, hosted by the Office of the Federal Public Defender, Northern District of California, and Contra Costa County Public Defender, Berkeley School of Law, Oakland, CA.
- Krane, D. October, 2015. Interpretation errors in DNA profiling. Biology Department Seminar Series, Wright State University, Dayton, OH.
- Krane, D. November, 2015. Examiner bias and mixture interpretation in DNA profiling. Legal Aid Society of New York, DNA College, Yeshiva University Law School, New York, NY.
- Krane, D. November, 2015. Probabilistic genotyping (as in TrueAllele®). Virginia Bar Association Capital Defense Workshop, Richmond, VA.
- Krane, D. December, 2015. Analyses of DNA profile databases. Cook County Public Defenders' Forensic DNA Unit, Chicago, IL.

- Adams, N. and D. Krane. February, 2016. Black boxes and due process:

 Transparency in expert software systems. Annual meeting of the American Academy of Forensic Sciences, Jurisprudence section platform presentation, Las Vegas, NV.
- Krane, D., Rowland, C. and N. Adams. February, 2016. Disputed DNA stats for a low-level sample: A case study. Annual meeting of the American Academy of Forensic Sciences, Jurisprudence section platform presentation, Las Vegas, NV.
- Adams, N., R. Chakraborty, C. Rowland and D. Krane. February, 2016. Complex mixtures and the minimum number of contributors: A case study (poster presentation). 68th Annual meeting of the American Academy of Forensic Sciences, Las Vegas, NV.
- N. Adams and D. Krane. February, 2016. Black Boxes and Due Process: Transparency in Expert Software Systems. 68th Annual Meeting of the American Academy of Forensic Sciences. Las Vegas, NV.
- D. Krane, C. Rowland and N. Adams. February, 2016. Disputed DNA Stats for a Low-level Sample: A Case Study. 68th Annual Meeting of the American Academy of Forensic Sciences. Las Vegas, NV.
- Krane, D. and A. Roth. April, 2016. Emerging legal issues surrounding DNA mixture statistics and probabilistic genotyping software. Northern District of California 2016 Judicial Conference, Napa Valley, CA.
- Krane, D. April, 2016. The Bridges to Success Initiative: Co-requisite remediation in the context of guided pathways and gateway mathematics courses. Ohio Department of Higher Education Convenings, Spitzer Conference Center (Lorain County Community College) and Sharonville Convention Center (Sharonville, OH).
- Krane, D. June, 2016. Attaching statistical weights to mixed samples where allelic dropout may have occurred. 17th annual Cook County Public Defenders' forensics forum, hosted by Loyola University Law School, Chicago, IL.
- Krane, D. June, 2016. Probabilistic genotyping: What is inside the black boxes? 17th annual Cook County Public Defenders' forensics forum, hosted by Loyola University Law School, Chicago, IL.
- Krane, D. July, 2016. The evolution of forensic DNA profiling. Biology Department seminar, University of Cincinnati, Cincinnati, OH.
- Krane, D. August, 2016. Solving the problem of mixed DNA profiles. 2016 Technology Transition Workshop, "Courtroom Knowledge," Duquesne University, Pittsburgh, PA.
- Krane, D. August, 2016. The case of WI vs. Avery: *Making a Murderer*. Wright State University Alumni College, Wright State University, Dayton, OH.
- Krane, D. September, 2016. Statistics and probabilistic genotyping. DNA Bootcamp, Hennepin County Public Defender's Office, Minneapolis, MN.

- Krane, D. October, 2016. The Bridges to Success Initiative: Technical assistance with course syllabi and remediation exercises. Ohio Department of Higher Education Convening at Ohio University, Dublin, OH.
- Krane, D. October, 2016. Problems with mixture interpretations. New York Legal Aid Society's DNA Unit Intensive Continuing Legal Education Training, "Questioning forensics: Inside the black box," Cordozo Law School, New York, NY.
- Krane, D. November, 2016. Probabilistic genotyping software. 2016 DNA Boot Camp, Office of the Federal Public Defender, Northern District of California and Office of the Public Defender, Contra Costa County. Federal Conference Center, Oakland, CA.
- Krane, D. December, 2016. The Bridges to Success Initiative: Technical assistance with student advising. Ohio Department of Higher Education Convening at Ohio University, Dublin, OH.
- Krane, D. February, 2017. Probabilistic genotyping. DNA Boot Camp 2017, Ninth Judicial Circuit with Central Florida Association of Criminal Defense Lawyers. Orlando, FL.
- Krane, D. February, 2017. Past and present DNA challenges. DNA Boot Camp 2017, Ninth Judicial Circuit with Central Florida Association of Criminal Defense Lawyers. Orlando, FL.
- N. Adams, and D. Krane. March, 2017. Quality Assurance for Software Development in DNA Forensics (poster). Second Annual Genetics in Forensics Congress. London, England
- N. Adams, and D. Krane. March, 2017. Maximum Allele Count Analysis on Novel Test Kits (poster). Second Annual Genetics in Forensics Congress. London, England.
- Krane, D. March, 2017. Advanced DNA. Capital Habeas Unit (CHU) National Conference. Omni La Mansion del Rio Hotel, San Antonio, TX.
- Krane, D. March, 2017. Complex DNA mixtures: Combined probability of inclusion, probabilistic genotyping software issues in innocence cases. They Blinded Me with "Science": Examining the Reliability of Forensic Evidence in Innocence Claims. Sheraton San Diego Hotel & Marina, San Diego, CA
- Krane, D. May, 2017. DNA statistics: PCAST's promise of a new era. Assessing Reliability: Forensic Evidence *after* PCAST. Seventeenth annual Cook County Public Defenders' forensics forum, hosted by Loyola University School of Law, Chicago, IL.
- Krane, D. June, 2017. Mixed DNA profiles, probabilistic genotyping and familial searching. Cuyahoga County Public Defender's Office, Cleveland, OH.
- Krane, D. November, 2017. Statistics and probabilistic genotyping. 2017 DNA Boot Camp, Office of the Federal Public Defender, Northern District of California and Office of the Public Defender, Contra Costa County. Federal Conference Center, Oakland, CA.

- Krane, D. November, 2017. Trace DNA and complex mixtures: Deconstructing the DNA findings. National Association of Criminal Defense Lawyer's 8th Annual Defending Sex Crimes Seminar, Las Vegas, NV.
- Krane, D. February, 2018. Testimony before the Ohio House of Representatives standing committee on Higher Education and Workforce Development regarding HB 66, Representative Mike Duffey, chair. Columbus, OH.
- Krane, D. March, 2018. Testimony before the Ohio House of Representatives Finance Committee subcommittee on Higher Education regarding HB 512, Representative Rick Perales, chair. Columbus, OH.
- Krane, D. and R. Blackburn. March, 2018. A major redesign of a gateway course at Wright State University. TxDLA (Texas Distance Learning Association), Dallas, TX.
- Krane, D. May, 2018. Outcomes of a major redesign of a STEM gateway course. Central State University Faculty Retreat, Springfield, OH.
- Krane, D. and R. Blackburn. June, 2018. Impact of course redesign on student achievement and engagement, NUTN webinar (archived at: https://bned.zoom.us/recording/share/s2JELhNeXSKMMb0YznRJuhZ42ljnT9 RbbYF8DQzCRbCwlumekTziMw).
- Krane, D. and C. Hughes. June, 2018. Probabilistic genotyping: Where are we now?. National Forensic College, Cardozo Law School, New York, NY.
- Krane, D. August, 2018. Forensic DNA profiling: What role should computers play in making judgement calls? Wright State University Alumni College keynote presentation, Dayton, OH.
- Krane, D. August, 2018. Forensic DNA profiling: What role should computers play in making judgement calls? Wright State University Alumni College keynote presentation, Dayton, OH.
- Krane, D. August, 2018. Complex DNA mixtures: Is the proof in the pudding? Louisiana Association of Criminal Defense Lawyers Forensics Seminar, Baton Rouge, LA.
- Krane, D., A Fraley, N. Guerrieri, and J. Gebhart. September, 2018. Reducing costs with improved results: A conversation with Dr. Dan Krane. National Association of College Auxiliary Services Webinar.
- Krane, D, N. Adams, and C. Hughes. September, 2018. Probabilistic genotyping: A two-day workshop. Los Angeles County Public Defenders' Office, Los Angeles, CA.
- Krane, D. November, 2018. Mixtures and probabilistic genotyping. DNA Boot Camp, Office of the Federal Public Defender, Northern District of California, Oakland, CA.
- Krane, D. November, 2018. Developments in DNA profiling. Death Penalty Seminar, Ohio Association of Criminal Defense Lawyers, Columbus, OH.

- Philpott, K., and D. Krane. February, 2019. The dawn of a new era: Probabilistic genotyping. 2019 Capital Case Defense Seminar, California Attorneys for Criminal Justice and the California Public Defenders' Association, Monterey, CA.
- Barlow, B., and D. Krane. February, 2019. The mixture problem. 2019 Capital Case Defense Seminar, California Attorneys for Criminal Justice and the California Public Defenders' Association, Monterey, CA.
- N. Adams, S. Lorenz, M. Babaeianjelodar, J. Matthews and D. Krane. February, 2019. Quantifying the impact of post-validation modifications to Forensic Statistical Tool. 71st Annual Meeting of the American Academy of Forensic Sciences. Baltimore, MD.
- Krane, D. March, 2019. History of forensic DNA uses and challenges. DNA Boot Camp 2019, Ninth Judicial Circuit with Central Florida Association of Criminal Defense Lawyers. Orlando, FL.
- Krane, D. March, 2019. Probabilistic genotyping. DNA Boot Camp 2019, Ninth Judicial Circuit with Central Florida Association of Criminal Defense Lawyers. Orlando, FL.
- Krane, D., and K. Wincko. April, 2019. Reducing costs with improved results: A conversation with Dr. Dan Krane. HLC Annual Conference, Chicago, IL.
- Krane, D. May, 2019. DNA comparisons. 2019 Judges' In-Court Seminar, United States District Court, District of Minnesota, Tofte, MN.
- Krane, D., J. Gebhart, N. Klingbeil, I. Mallett, A. Steele-Middleton, and D. Palmer July, 2019. Reducing costs with improved results: Inclusive Access at Wright State. Ohio Affordable Learning Summit, Ohio Dominican University, Columbus, OH.
- Krane, D. October, 2019. Attaching statistical weights to forensic DNA profiling results. 2019 DNA Workshop, Georgia Public Defender Council, Atlanta, GA.
- Krane, D. October, 2019. Probabilistic genotyping: an approach to attaching statistical weights to mixed samples where allelic dropout may have occurred. 2019 DNA Workshop, Georgia Public Defender Council, Atlanta, GA.
- Krane, D. November, 2019. Attaching statistical weights to forensic DNA profiling results. 2019 DNA Boot Camp, Office of the Federal Public Defender, Northern District of CA and Contra Costa County Public Defender, Oakland, CA.
- Krane, D. November, 2019. Mixed DNA profiles and probabilistic genotyping. 2019 DNA Boot Camp, Office of the Federal Public Defender, Northern District of CA and Contra Costa County Public Defender, Oakland, CA.
- Krane, D. November, 2019. Complex DNA analysis: Low-level and mixed-source samples. Selected Problems in Criminal Justice Administration: Law and Forensic Science (hosted by Keith Findley and Jo Handelsman), University of Wisconsin, Madison, WI.

Presentations (continued):

- Krane, D. January, 2020. Probabilistic genotyping software (PGS): Paradigm shift in DNA mixture interpretation. Questioning Forensics, Brooklyn Law School Forchelli Center, Brooklyn, NY.
- Krane, D. January, 2020. Probabilistic genotyping. Forensic Algorithms Working Group (https://www.gao.gov/products/GAO-20-479SP), U.S. Government Accountability Office, Washington, DC.
- Krane, D. March, 2020. Evaluating complex, low-level DNA mixtures. Selected Problems in Criminal Justice Administration: Law and Forensic Science (hosted by Keith Findley and Jo Handelsman), University of Wisconsin, Madison, WI.
- Krane, D. November, 2020. Probabilistic genotyping: The dawn of a new era in DNA profiling. 28th Annual Capital Defense Workshop, The Virginia Bar Association, virtual event.
- Krane, D. April, 2021. Using probabilistic genotyping to attach a statistical weight to mixed DNA profiles. Selected Problems in Criminal Justice Administration: Law and Forensic Science (hosted by Keith Findley and Jo Handelsman), University of Wisconsin, Madison, WI.
- Krane, D. November, 2021. Probabilistic genotyping: The dawn of a new era in DNA profiling. Ohio Public Defender Conference, virtual event.
- Krane, D. March, 2022. How a Crime Lab Generates a Forensic DNA Profile. Wisconsin Forensic University -- Handling DNA Evidence, Pewaukee, WI.
- Krane, D. March, 2022. Observer Effects and Confirmation Bias. Wisconsin Forensic University -- Handling DNA Evidence, Pewaukee, WI.
- Krane, D. March, 2022. Statistical Weights of Single Source and Mixed DNA Profiles. Wisconsin Forensic University -- Handling DNA Evidence, Pewaukee, WI.
- Krane, D. March, 2022. An Introduction to Probabilistic Genotyping. Wisconsin Forensic University -- Handling DNA Evidence, Pewaukee, WI.
- Krane, D. June, 2022. Generating Forensic DNA Profiles. Forensic DNA CLE Program, New Mexico Criminal Defense Lawyers Association, Santa Fe, NM.
- Krane, D. June, 2022. Observer Effects and Confirmation Bias in DNA Profiling. Forensic DNA CLE Program, New Mexico Criminal Defense Lawyers Association, Santa Fe, NM.
- Krane, D. June, 2022. Single Source and Mixed DNA Profile Statistics. Forensic DNA CLE Program, New Mexico Criminal Defense Lawyers Association, Santa Fe, NM.
- Krane, D. June, 2022. Probabilistic Genotyping: The Dawn of a New Era in DNA Profiling. Forensic DNA CLE Program, New Mexico Criminal Defense Lawyers Association, Santa Fe, NM.
- Rowland, C., and Krane, D. January, 2023. Challenges associated with interpreting mixed DNA profiles. 2023 DNA Boot Camp, Office of the Federal Public Defender, Northern District of CA and Contra Costa County Public Defender, Sacramento, CA.

Presentations (continued):

- Rigby, K., and Krane, D. February, 2023. Defending against DNA evidence. Litigating Common Forensic Issues, Forensic Training Unit, Office of the Ohio Public Defender, Columbus, OH.
- Krane, D., and S. Ford. March, 2023. A letter from America: A view of DNA evidence from the other side of the pond. Doughty Street Chambers, London, England.
- Krane, D., and S. Ford. March, 2023. A letter from America: A view of DNA evidence from the other side of the pond. Kingsley-Napley Solicitors, London, England.
- Krane, D., and Adams, N. March, 2023. Probabilistic genotyping software (parts 1 and 2). DNA in 2023 and Beyond, Ninth Judicial Circuit with Central Florida Association of Criminal Defense Lawyers. Orlando, FL.
- Krane, D., and S. Ford. April, 2023. A letter from America: A view of DNA evidence from the other side of the pond. London Criminal Courts Solicitors' Association (LCCSA), London, England.
- Rigby, K., and Krane, D. May, 2023. DNA evidence and working with a forensic expert. Death Penalty Training, Ohio State Bar Association, Columbus, OH.
- Krane, D. May, 2023. The science (and pseudoscience) of DNA profiling. Dayton Regional STEM School, Dayton, OH.
- Ford, S., Adams, N, and Krane, D. July, 2023. An introduction to probabilistic genotyping. Indiana Public Defender Probabilistic Genotyping Training Program, Indianapolis, IN.
- Krane, D. July, 2023. An exploration of factor space as part of internal validation of probabilistic genotyping systems. Indiana Public Defender Probabilistic Genotyping Training Program, Indianapolis, IN.
- Krane, D. August, 2023. The basics of DNA mixtures. Wisconsin Forensic University Probabilistic Genotyping, Pewaukee, WI.
- Krane, D. August, 2023. Complex mixtures and likelihood ratios. Wisconsin Forensic University Probabilistic Genotyping, Pewaukee, WI.
- Krane, D. August, 2023. Evaluating validation: Exploration of factor space. Wisconsin Forensic University Probabilistic Genotyping, Pewaukee, WI.
- Krane, D. September, 2023. The science (and pseudoscience) of DNA profiling. Bellbrook High School Bioengineering Program, Bellbrook, OH.
- Krane, D. September, 2023. Forensic DNA profiling. Lawyers Club of Cincinnati, Cincinnati, OH.
- Krane, D. October, 2023. Introductory DNA for the trial attorney. Plenary session, Texas Criminal Defense Lawyers Association, 20th Annual Forensics Seminar, Austin, TX.
- Krane, D. October, 2023. Advanced issues in DNA profiling (including genetic genealogy). Texas Criminal Defense Lawyers Association, 20th Annual Forensics Seminar, Austin, TX.

Presentations (continued):

- Krane, D. October, 2023. The dawn of probabilistic genotyping. Northern Nevada DNA Bootcamp, Washoe County, NV.
- Krane, D. November, 2023. Evaluating complex, low-level DNA mixtures. Selected Problems in Criminal Justice Administration: Law and Forensic Science (hosted by Professors Keith Findley and Jo Handelsman), University of Wisconsin, Madison, WI.

Graduate students and post-doctoral fellows mentored:

- David P. Hostler, III. 1993-1995, M.S.: The dependence of rate and mode of evolution on genomic context within primates.
- Adam P. Skepner. 1994-1996, M.S.: The application of random amplification of polymorphic DNA to phylogenetic reconstructions.
- Keri Steinbrugge. 1994-1997, M. S. candidate: The role of the predominant SINE within lagomorph genomes.
- Krista E. Bloniarz. 1995-1996, M.S., non-thesis option: The application of RAPD-PCR in genome analyses.
- Cynthia Kiefer. 1996-1999, M.S., non-thesis option: The influence of genome compartmentalization on nucleotide substitutions.
- Allen J. York. 1997-2000, M.S. candidate: The subfamily relationships and functional roles of repetitive elements.
- Dalana Barnett. 1997-2000, M. S. recipient: Characterization of a novel, short and highly repeated sequence in carnivores.
- Terry Oroszi. 1998-2000, M.S. candidate: Characterization of a novel, short and highly repeated sequence in pigs.
- Billy Grunwald. 1998-present, M.S. candidate: Utilization of genetic diversity measures a means of assessing terrestrial environmental impacts.
- John F. Sojda, III. 1999, post-doctoral research fellow: Sequence variation in the superoxide dismutase gene in Caribbean *Drosophila* populations.
- Emmanuel Aigbokhan. 1999-2000, post-doctoral research fellow: Utilization of genetic diversity measures a means of assessing aquatic environmental impacts.
- Lee Ott. 1999-2002, M.S. recipient: Genetic population structures of Pacific Coast herring populations exposed to anthropogenic stressors.
- Erin Newburn. 1999-2002. M.S. recipient: Molecular identification of Chironomid species.
- Balasubramanian Abiramikumar. 1999-2003. M.S. recipient: Characterization of a novel, short and highly repeated sequence in African elephants.
- Michael C. Kuneman. 2001-2003. M.S., non-thesis: Progress in understanding genetic diversity: The use of genetic diversity for assessment, conservation and protection purposes.

Graduate students and post-doctoral fellows mentored (continued):

- Randall J. Loges. 2000-2003. M.S. candidate: Genetic diversity and characterization of *Hyallela azteca* from Ohio, Montana and commercial suppliers.
- Krista Jastremski. 2000-2004. M.S. recipient: Changes in genetic diversity within pill bug populations at historically impacted terrestrial sites.
- Norman Scott Blair. 2000-2004. M.S. candidate: Molecular characterization of the sex of Great Lakes birds.
- Joseph Bartozcek. 2001-2010. Biomedical Sciences Ph. D. recipient: Effects of habitat loss/fragmentation on Ambystomatid salamanders.
- Esley Heizer. 2003-2005. M.S. recipient: Correlation between major codon usage and amino acid biosynthetic costs in eight prokaryotic species.
- Monita Sharma, 2004-2006, M.S. recipient: Molecular characterization of chironomid species.
- Peichang Shi, 2006, M.S., non-thesis option: Gene expression patterns as an indicator of exposure to environmental stresses.
- Chad Ferguson, 2004-2009, Environmental Sciences Ph. D. recipient: Using chironomids for environmental impact assessment.
- Nina Archie, 2004-2006, M.S. recipient: Characterization of n+4 stutter artifacts in forensic DNA profiles.
- Esley Heizer. 2005-2010. Biomedical Sciences Ph.D. recipient: Correlation between major codon usage and amino acid biosynthetic costs in prokaryotes and eukaryotes.
- Uohna Foster, 2010-2013, Biomedical Sciences Ph.D. candidate: Persistance and transfer of forensic DNA samples.
- Taryn Hunt, 2011-2014, M.S. recipient (non-thesis option): Laundry transfer of DNA from epithelial cells.
- Erin Berdanier, 2011-2016, M.S. recipient: Laundry transfer of DNA from blood stains.

Graduate thesis committees served upon:

Keri Pedly. 1993-1994. M.S. recipient.

Liang Shi. 1993-1996. Ph.D. recipient.

Melissa Goldman. 1994-1996. M.S. recipient.

Lou Li. 1994-1997. Ph.D. recipient.

Adrienne Moran. 1994-1996. M.S. recipient.

Steve Hendrix. 1994-1996. M.S. recipient.

David Brown. 1994-1996. M.S. recipient.

Michelle Malotte. 1994-1999. Ph.D. recipient.

David Ellis. 1995-2000. M.S. student.

Scott Rousch. 1995-1997. M.S. recipient.

Graduate thesis committees served upon (continued):

Elizabeth Smucker. 1996-1999. M.S. recipient.

David Sternberg. 1995-2002. M.S. recipient.

Deborah Vallance. 1995-1996. M.S. student.

Andrea Alexander. 1999-2002. M.S. recipient.

Patricia Morgan. 1997-present. Ph.D. candidate.

Billy Grunwald. 1998-2001. M.S. student.

Terry Oroszi. 1998-2001. M.S. student.

Kelly Jo Peterson. 1998-2003. Ph.D. recipient.

Lee Ott. 1999-2002. M.S. recipient.

Erin Newburn. 1999-2002. M.S. recipient.

Balasubramanian Abiramikumar. 1999-2003. M.S. recipient.

Norman Scott Blair. 2000-2005. M.S. candidate.

Randall Loges. 2000-2004. M.S. candidate.

Marc Greenberg. 2001-2002. Ph.D. recipient.

Michael C. Kuneman. 2001-2003. M.S. recipient.

Joseph Bartozcek. 2001-present. Ph.D. candidate.

David Paoletti. 2001-2006. Ph.D. recipient.

Gina Cooper. 2001-2009. Ph.D. recipient.

Jason Gilder. 2001-2003. M.S. recipient.

Sundeep "Sunny" Anand. 2001-2003. M.S. recipient.

Sharon Reilly. 2002-2004. M.S. candidate (non-thesis option).

Prashanth Athri. 2002-2004. M.S. recipient.

Balasubramanian Abiramikumar. 2002-2004. M.S. recipient.

Jeanette Frey. 2003-2005. M.S. recipient.

Esley Heizer. 2003-2005. M.S. recipient.

Doug Raiford. 2003-2005. M.S. recipient.

Ryan Flynn. 2003-2009. M.S. recipient (non-thesis option).

Sridhar Ramachandran. 2003-2007. Ph.D. recipient.

Jason Gilder. 2004-2007. Ph.D. recipient.

Monita Sharma. 2004-2007. M.S. recipient.

Doug Raiford. 2005-2008. Ph.D. recipient.

Chad Ferguson. 2004-2010. Ph.D. recipient.

Esley Heizer. 2005-2010. Ph.D. recipient.

Peichang Shi. 2006. M.S. recipient (non-thesis option).

Graduate thesis committees served upon (continued):

Adam Guess. 2007-2008. M.S. recipient.

Amanda Hanes. 2007-2009. M.S. recipient.

Sushant Taksande. 2008-present. M.S. candidate.

Uohna Foster. 2010-2013. Ph.D. candidate.

Taryn Hunt. 2011-2014. M.S. recipient.

Erin Berdanier. 2011-2016. M.S. recipient.

Undergraduate honors thesis advisees:

Carri Eagler: 1993-1996. Libby Provci: 1994-1996.

Michelle Gnam: 1994-1996. Jeanne Uy: 1994-1996

Michelle Lawhun: 1995-1998. Lora Dodson: 1996-1998.

Jason Soderquist: 1997-1999. Elizabeth Zimmer: 1998-1999.

 Sarah Schmidt: 2000-2001.
 Melissa Strain: 2000-2001.

 Denada Sharra: 2001-2004.
 Roger Fecher: 2005-2006.

Leah Kershner: 2007-2009. Krista Dona: 2013-2015.

Courses taught/developed:

- Molecular Genetics (BIO 211 and 2110). An introduction to molecular biology and genetics for majors in Biological Sciences at Wright State University. Winter, 1994 through 2012; Summer 1998 through 2012; Spring 2020 and 2021.
- Cells and Genetics (BIO 112). An introduction to biology for majors in Biological Sciences at Wright State University. (Extensively redeveloped in Summer, 1993) Fall, 1994 through 2000; 2002; 2008 through 2010.
- Molecular and Cell Biology Laboratory (BIO 410). An introduction to molecular and cell biology laboratory techniques for majors in Biological Sciences at Wright State University. (Developed course in Winter, 1994) Spring, 1994; (redeveloped in Spring, 2003) Spring, 2003.
- Molecular Evolution (BIO 461/661). A senior/graduate level course describing the basis of evolutionary inferences using molecular data including phylogenetic reconstruction and mutational tendencies. Biological Sciences at Wright State University. (Developed course in Winter, 1995) Spring, 1996, 1997, 1999, 2001, 2004 and 2007.
- Population Genetics (BIO 460/660). A senior/graduate level course focusing on the statistical basis of changes in allele frequencies within populations of organisms. Biological Sciences at Wright State University. (Developed course in Winter, 1998) Spring, 1998, 2000, and 2003.
- Human Genetics (BIO 426/626). A senior/graduate level course on the special considerations and approaches used to study the patterns of inheritance in humans. Biological Sciences at Wright State University. (Developed course in Winter, 2002) Spring, 2002.

Courses taught/developed (continued):

- Advanced Cell Biology (BMS 991/BIO 701). An advanced literature based course survey on the principles of cell structure and function for incoming biomedical sciences PhD students and graduate students in Biology. (Co-developing course in Summer, 1998) Fall, 1998 and 1999.
- Introduction to Research Biology (BIO 702). A graduate level course on current research in biological sciences at Wright State University. Fall, 1993 and 1996.
- Independent Studies in Biology (BIO 499). A senior level course of guided independent, laboratory research for majors in Biology. Winter, 1994 to present.
- Introduction to Bioinformatics (BIO 371/CS 271). A sophomore level course that introduces computer science and biology majors to the most important algorithms and current problems in bioinformatics. Spring, 2002 through 2012.
- Bioinformatics algorithms (BIO 471/CS 471). A senior level, capstone course focusing on algorithm development for biology and computer science students in the Wright State bioinformatics program. Fall, 2002 through 2011.
- Honors Genetics (BIO 119). A course featuring selected readings on genetics and evolution for Honor's students. Biological Sciences at Wright State University. (Developed course in Summer, 1994) Fall, 1994 through 2000; 2002, 2004 through 2010.
- Bioinformatics algorithms (BIO 4710/CS 4710). A senior level, capstone course focusing on algorithm development for biology and computer science students in the Wright State bioinformatics program. Fall, 2012.
- Cells and Genetics (BIO 1120). An introduction to biology for majors in Biological Sciences at Wright State University. (Co-taught with Dr. Emily Kramer) Fall, 2012.
- Cells and Genetics (BIO 1120). An introduction to biology for majors in Biological Sciences at Wright State University. Fall, 2013, Fall 2015, Fall 2016, Fall 2017 (as a major revision including transition to a new textbook and implementation of co-remediation sections), Summer 2018, Fall 2018, Summer 2020, Fall 2022, Summer 2023, and Fall 2023.
- Honors Genetics (BIO 1190). A course featuring selected readings on genetics and evolution for Honor's students. Biological Sciences at Wright State University. Fall, 2012, 2013, 2015, 2016, 2017, 2018, and 2023.
- First Year Seminar (UVC 1010). A course introducing incoming students to college life. University College, Wright State University. Fall, 2012 and 2013.
- Senior Seminar (BIO 4920). A capstone course on presenting scientific information. Biological Sciences at Wright State University. Summer, 2013 through 2018.
- Introduction to Bioinformatics (BIO 3710/CS 2710). A sophomore level course that introduces computer science and biology majors to the most important algorithms and current problems in bioinformatics. Spring, 2013 and 2014.

Courses taught/developed (continued):

- Forensic DNA Profiling (BIO 3710/ATH 3800). Application of critical thinking skills to forensic DNA profiling in a scale-up setting. Cross-listed in Biology and Anthropology at Wright State University. Spring, 2013, 2014, 2016 (developed as a 100% on-line course in 2016), Springs 2017 to 2024.
- Health and Disease (BIO 1070). An introductory Biology course for non-majors about how the human body functions and the social, political, and cultural aspects of public health. Developed and taught, Spring 2023 and 2024.

Academic service at Wright State University:

- Biological Sciences Molecular and Cell Biology Curriculum Development Committee, 1993 to present.
- Science Apprenticeship Program for Women and Minority Students (mentor and co-investigator, Prem Batra founding program director), 1994 to 2005.
- Short Term Research Experience/Access for Minority Students (STREAMS) (faculty advisor and co-investigator, Robert Putnam program director), 1994 to 2003.
- Computer-assisted Learning Center Committee (elected chair), 1993 to 1996.
- Ohio Science Fair Judge and Awards Presenter, 1994 to 1997.
- Biological Sciences Seminar Program Committee, 1994 to 2019, and 202 to 2024 (Chair in 2005 to 2011).
- College of Science and Mathematics Computer Network Facilitation Committee, 1994 to 1996
- Biomedical Sciences PhD Program Nomination Committee, elected to terms running from 1994 to 1996, from 2005 to 2007 and from 2009 to 2011.

Developmental Biology Search Committee, 1994.

Biology Departmental Honors and Scholarships Committee, 1995 to 2001.

Cell Biology Search Committee, 1995.

Research and Sponsored Programs Associate Director Search Committee, 1995.

University Resident Life Committee, 1995 to 1996.

Computer-assisted Learning Center Committee, 1996 to 1999.

Space and Equipment Allocation Committee, 1997 to 2000.

Faculty liaison for Wright State University's varsity baseball team, 1997 to present.

University Commencement Committee, 1998 to 2000.

University Honors' Committee, 1998 to 2001.

Biological Sciences Undergraduate Curriculum Committee, 1998 to 2001; 2003 to 2005; 2007 to 2009.

Plant Physiologist Search Committee, 1998.

Academic service at Wright State University (continued):

College of Science and Mathematics Faculty Development Committee, elected 1999 to 2001; Appointed Biology Department Representative for 2007-2008 and for 2008-2009 and for 2012-2013.

Cell/Molecular Biologist Search Committees, 2000; 2008 (co-chair).

Information Technology Research Initiative, Research Committee, 2000 to 2004.

College of Science and Mathematics Scholarships Committee, 2000 to 2001.

College of Science and Mathematics Dean Search Committee, 2001 to 2002.

Assistant to the Director (Technology Transfer) of the Office of Research and Sponsored Programs Search Committee, 2002.

Aquatic Biologist Search Committee, 2002-2003.

University Athletics Council, elected to terms running from 2002 to 2004 and 2005 to 2006; Faculty Senate Appointee 2006 to 2007 (elected Vice-Chair in 2006 to 2007; elected Chair 2009-2011; past-chair 2011-2013); Senate representative (2013-2015).

Athletics Council Pre-game Lecture Committee (chair), 2007-2014.

Athletics Council Blackboard to Backboard Challenge Committee (2010-2013).

Athletics Council Gender Equity Sub-committee, 2003 to 2006, and 2008-2011.

Athletics Council Team Liaison Sub-committee, 2002 to 2008.

Athletics Council Athletic Director Review Sub-committee, 2002-2007 (Chair in 2005-2006).

Athletics Council Constitution and By-laws Sub-committee, 2006-2008 and 2018-2020 (Chair).

Athletics Council Student Welfare Committee, 2009-2014.

Research and Sponsored Programs Technology Transfer Director Search Committee, 2007.

Cell/Molecular Biologist Search Committee, 2007-2008 (Chair in 2008).

Steering Committee, College of Science and Mathematics, elected 2006 to 2007 and 2008 to 2009 (elected Chair for 2007-2008, 2008-2009, 2009-2010, 2010-2011 and 2011-2012 academic years).

Vice President for Advancement Search Committee, 2008.

College of Science and Mathematics Academic Mediation Committee, 2007-present.

College of Science and Mathematics representative (elected) to the Wright State University Faculty Senate, 2009-2010.

Director of the Wright State University Ervin J. Nutter Center Search Committee, 2010.

Wright State University representative to the Ohio Faculty Council (secretary), 2010-2012.

Academic service at Wright State University (continued):

Wright State University representative to the Ohio Faculty Council (vice chair), 2012-2013.

Wright State University representative to the Ohio Faculty Council (chair), 2013-2019.

Faculty Senate ad hoc Committee on the Master Planning Process (chair), 2010-2011.

Semester Conversion Director Search Committee, 2010.

University Commencement Committee, 2011-2014.

Graduate Council, 2011-2014.

Vice President for Business and Fiscal Affairs Search Committee, 2011.

University Faculty Budget Priority Committee (chair), 2010-2014, 2016-2019.

Faculty Senate Executive Committee (chair), 2010-2014, 2015-2019.

Faculty Senate ad hoc committee on First Year Seminars, 2012-2014.

University President's Cabinet, 2012-2014.

University Mission Driven Allocation Budget Model Executive Committee, 2012-2014.

University Diversity Advisory Council, 2012-2014.

Permanent Provost Search Committee, 2012-2013.

Academic Integrity Conduct Review Panelist, 2012-2013.

President-elect of the Wright State University Faculty, 2010-2011.

President of the Wright State University Faculty, 2011-2014 and 2019-2021.

Wright State University Task Force on Affordability and Efficiency, chair, 2015-2019.

Wright State University Foundation Archives Mini-campaign, Executive leadership team member, 2016-2018.

Wright State University Foundation 360-review, 2016-2017.

State of Ohio Representative to Complete College America, 2016-2018.

Ohio's Complete College America Co-requisite Work Plan Committee, 2016-2017.

Vice President of the Wright State University Faculty, 2017-2019.

Faculty Senate Textbook Affordability ad hoc committee, chair, 2017.

University Undergraduate Academic Policies Committee, chair, 2017-2019.

University Undergraduate Student Success Committee, chair, 2017-2019.

University Program Effectiveness Review Committee, co-lead, 2017-2019.

Ohio's Complete College America Co-requisite Work Plan Committee, 2016-2017.

Faculty Senate Textbook Affordability ad hoc committee, chair, 2017, 2018.

University Undergraduate Student Success Committee, chair, 2017-2019.

University Program Efficiency Review Committee, co-lead, 2017-2019.

Academic service at Wright State University (continued):

University Assurance of Learning Committee, Faculty representative, 2018-2019.

University Seat Management Committee, co-chair, 2018-2019.

University Strategic Enrollment Steering Committee, Senate representative, 2017-2019.

Ohio Department of Higher Education Transfer Assurance Guarantee Steering Committee, Faculty representative, 2018-2019.

Wright State Summer Forensic Science Camp coordinator, 2014-2019.

University Promotion and Tenure Committee, 2019-2020.

Clinical Lab Sciences Director Search, co-chair, 2022-2023.

Clinical Lab Sciences Instructor Search, co-chair, 2022-2024.

Wright State College of Graduate Programs and Honors Studies RISE Tour Criminology and Forensic Science, co-chair, 2023.

Biological Sciences Department Faculty Development Committee, chair, 2023-2024.

Court recognized expert in DNA profiling:

Missouri vs. Nethery (St. Charles, MO, 1991).

Iowa vs. Ripperger (Burlington, IA, 1992).

North Carolina vs. Fisher (Charlotte, NC, 1992).

Illinois vs. Tynes (Kankakee, IL, 1992).

Nebraska vs. Bundy (Columbus, NE, 1992).

North Carolina vs. White (Edenton, NC, 1993)

North Carolina vs. Jones (Winnsboro, NC, 1993).

Ohio vs. Honzu (Columbus, OH, 1994).

Ohio vs. Saylors (Urbana, OH, 1994).

Ohio vs. McGuire (Dayton, OH, 1994).

Ohio vs. Brewer (Hillsoboro, OH, 1995).

South Carolina vs. Eubanks (Columbia, SC., 1995).

Ohio vs. Parks (Columbus, OH, 1995).

Ohio vs. Oldham (Hamilton, OH, 1995).

California vs. Strange (Nevada City, CA, 1996).

California vs. Wenger (Long Beach, CA, 1996).

United States vs. Lowe (First Circuit, Boston, MA, 1996).

Washington vs. Gore (Seattle, WA, 1996).

Virginia vs. Gray (Martinsville, VA, 1996).

Kentucky vs. Tipton (Stanton, KY, 1997).

California vs. Allen (Compton, CA, 1997).

Virginia vs. Brogan (Roanoke, VA, 1998).

Missouri vs. Taylor (St. Louis, MO, 1998).

Ohio vs. Sapp (Springfield, OH, 1998).

Missouri vs. White (St. Louis, MO, 1998).

Indiana vs. Smith (Middletown, IN, 1999).

Indiana vs. Jones (Vincennes, IN, 2000).

Florida vs. Esty (Pensacola, FL, 2000).

Indiana vs. Williams (Terre Haute, IN, 2001).

Minnesota vs. Roman Nose (St. Clair, MN, 2001).

Massachusetts vs. Greineder (Welsley, MA, 2001).

Indiana vs. Wilburn (Covington, IN, 2001).

South Dakota vs. Luce (Aberdeen, SD, 2002).

Minnesota vs. Bailey (Minneapolis, MN, 2002).

California vs. Howard (Los Angeles, CA, 2002).

California vs. Quinones (San Francisco, CA, 2002).

Minnesota vs. Traylor (Minneapolis, MN, 2002).

Ohio vs. Knott (Athens, OH, 2002).

Indiana vs. Guffey (Tipton, IN, 2002)

Indiana vs. Ward (Rockport, IN, 2002).

California vs Robinson (Sacramento, CA, 2003).

New Mexico vs. Arviso (Farmington, NM, 2003).

California vs. Cheung (Orange County, CA, 2003).

Ohio vs. Henderson (Athens, OH, 2003).

Ohio vs. Fears (Lebanon, OH, 2003).

Maryland vs. Daniels (Frederick and Rockville, MD, 2003).

United States vs. Zephier (Sioux Falls, SD, 2003).

Montana vs. Jones (Lewistown, MT, 2004).

Indiana vs. Cooper (Goshen, IN, 2004).

New Mexico vs. Garcia (Albuquerque, NM, 2004).

New York vs. Alvarez (Schenectady, NY, 2004).

Ohio vs. Hines (Cleveland, OH, 2004).

Victoria State Coroner's Inquest into the Death of Jaidyn Leskie (Melbourne, Victoria, Australia, 2004 and 2005)

Montana vs. Misner (Great Falls, MT, 2005).

California vs. Avila (Orange County, CA, 2005).

Minnesota vs. Bailey (Minneapolis, MN, 2005).

United States vs. Jenkins (Washington DC District Court, 2005).

Iowa vs. LaMasters (Waterloo, IA, 2005).

Minnesota vs. Temple (Minneapolis, MN, 2005).

Michigan vs. Leiterman (Ann Arbor, MI, 2005).

Michigan vs. Spagnola (2nd Circuit Court of Appeals, Benton Harbor, MI, 2005).

Ohio vs. McClure (Batavia, OH, 2005).

Virginia vs. Davis (Norfolk, VA, 2005).

Maryland vs. Derr (La Plata, MD, 2006).

Colorado vs. Brownlow (Adams County, CO, 2006).

Maryland vs. Odom (Prince George's County, MD, 2006).

Virginia vs. Riddick (Hampton Circuit Court, Hampton, VA, 2006).

Illinois vs. Rivera (Chicago, IL, 2006).

California vs. Robinson (Los Angels, CA, 2006).

Regina vs. Sean Hoey (Northern Ireland High Court, Belfast, NI, 2006).

Arizona vs. Bigger (Tucson, AZ, 2007).

Ohio vs. Matthews (Xenia, OH, 2008).

United States vs. Davis (US District Court of MD, 2008).

United States vs. Garner (Fort Eustis, VA, 2008).

United States vs. Hennis (Fort Bragg, NC, 2008).

Colorado vs. Tunis (Golden, CO, 2008).

Regina vs. Broughton (Oxford Crown Court, Oxford, England, 2009)

California vs. Smith (Sacramento, CA, 2009).

New York vs. Megnath (Queens, NY, 2009).

Virgin Islands vs. Xavier (St. Croix, Virgin Islands District Court, 2010).

Regina vs. Canning (Belfast Crown Court, Belfast, Northern Ireland, 2010).

Regina vs. Broughton (Oxford Crown Court, Oxford, England, 2010).

Regina vs. Walsh (Belfast Crown Court, Belfast, Northern Ireland, 2011).

Colorado vs. Rodriquez (Golden, CO, 2011).

Illinois vs. Gonzalez (Chicago, IL, 2011).

Regina vs. Duffy and Shivers (Belfast Crown Court, Belfast, Northern Ireland, 2011).

Regina vs. Dos Santos (Central Criminal Court, London, England, 2012).

Oregon vs. Garrett (Portland, OR, 2012).

Regina vs. Deacon (Central Criminal Court, London, England, 2013).

United States vs. McCluskey (US District Court of AZ, 2013).

Regina vs. Dos Santos (Central Criminal Court, London, England, 2013).

Regina vs. Colhoun (Newry Crown Court, Newry, Northern Ireland, 2013).

Ohio vs. McKenna (Dayton, OH, 2014).

Regina vs. Colhoun (Newry Crown Court, Newry, Northern Ireland, 2014).

Missouri vs. McBenge (St. Charles, MO, 2014).

United States vs. Henning (Fort Leavenworth, KS, 2015).

United States vs. Smalls (Brooklyn, NY, 2015).

New York vs. James (Staten Island, NY, 2015).

New York vs. Hillary (Canton, NY, 2016).

Regina vs. Simms (Oxford Crown Court, England, 2016).

Washington vs. Fair (Seattle, WA, 2017).

Illinois vs. Flores-Mora (Chicago, IL, 2017).

United States vs. Fell (US District Court of VT, 2017).

New York vs. Rochard (New York, NY, 2017).

Regina vs. Hussain (Central Criminal Court, London, England, 2017).

Florida vs. Clark (Palm Beach, FL, 2017).

Regina vs. Abbas Uddin (Norwich Crown Court, England, 2018).

United States vs. Oldman (Casper, WY, 2018).

United States vs. Elmore (San Francisco, CA, 2019).

United States vs. Gissantaner (Grand Rapids, MI, 2019).

United States vs. Lewis (Minneapolis, MN, 2019).

Colorado vs. Root (Denver, CO, 2019).

Andersen vs. City of Chicago (Chicago, IL, 2020).

Texas vs. Colone (Beaumont, TX, 2020).

Texas vs. Escobar (Austin, TX, 2020).

Regina vs. Trotter (Croydon Crown Court, England, 2020).

United States vs. Cooke (Wilmington, DE, 2022).

New York vs. Burrus (New York, NY, 2022).

United States vs. Cortorreal (New York, NY, 2022-2023).

United States vs. Cutbank (Minneapolis, MN, 2023).

Washington vs. Nicholas (Seattle, WA, 2023).

Georgia vs. Deeds (Eastman, GA, 2023).

Hawaii vs. Thompson (Honolulu, HI, 2023).

Texas vs. Colone (Beaumont, TX, 2023).

United States vs. Ortiz (San Diego, CA, 2024).

Professional service:

- Featured appearances on "20/20," "Court TV," "CBS Nightly News," "Unsolved Mysteries," "BBC Newsnight," "BBC Panorama," "CBS's 48 Hours," "True Crime" podcast, and numerous appearances on all Dayton-area local TV broadcasts.
- Technical consultant for "Court TV," "CBS Nightly News," NBC's "Unsolved Mysteries," CBS's "Sixty Minutes," CBS's "Eye to Eye with Connie Chung," the Gannette News Service, "Weekly Reader Magazine," "The Washington Post," "The Los Angeles Times," and "The Dayton Daily News."
- Reviewer for the journals: "Appraisals," "Molecular Biology and Evolution," "Genetics," "Genomics," "Journal of Molecular Evolution" "The American Biology Teacher," "IEEE Bioinformatics," and "Accountability in Research."
- Presiding officer, Animal Molecular Biology Section, Ohio Academy of Science 107th Annual Meeting at Miami University-Middletown, April 1998.
- Review panel member, U. S. Environmental Protection Agency "Ecological Indicators Panel," 1999, 2000, 2001, 2002, 2004 and 2006.
- Review panel member, U. S. Environmental Protection Agency "Nanotechnology Panel," 2006.
- Ad hoc reviewer for the Hudson River Foundation, 2002 and 2004.
- Fairness in Forensics," with Roger Koppl, op ed published in several newspapers, 12-17 August 2008, including Newark Star-Ledger, The Olympian (Olympia, Washington), Hartford Courant (Sunday edition), Herald-Leader (Lexington, Kentucky; Sunday edition), Lake Wylie Pilot (Lake Wylie, South Carolina), Daily Herald (Provo, Utah), The Modesto Bee (Modesto, California), Tri-city Herald (south-central Washington), The News & Observer (Raleigh, Durham, and Chapel Hill, North Carolina), Belleville News-Democrat (Belleville, Illinois), The Bellingham Herald (Bellingham, Washington), The Fresno Bee (Fresno, California) and the Anchorage Daily News.
- "Science Rules the FBI Should Obey," with Roger Koppl, op ed published in several newspapers, 13-16 January 2010, including the Cleveland Plain Dealer, Fort Worth Star-Telegram Press Democrat (Santa Rosa, California), Bradenton Herald (Florida), Wake Forest News & Observer, The News Tribune (Tacoma, Washington), and The Fresno Bee (Fresno, California).
- David R. Hopkins and Dan E. Krane, "Higher education: An investment guaranteed to pay off." An op-ed piece published in major newspapers in Ohio during the month of September, 2013.
- David R. Hopkins and Dan E. Krane, "Education An equal opportunity path to the American dream." An op-ed piece published in major newspapers in Ohio during the month of November, 2013.

Professional service (continued):

- National Event Supervisor (Forensic Science), Science Olympiad, Wright State University, Dayton, OH 2013.
- Gubernatorial appointee, Forensic Chemistry Representative to the Scientific Advisory Committee for the Virginia Department of Forensic Science. (appointed by Governor Mark Warner for a term of 2005-2006; reappointed by Governor Tim Kaine for a term of 2006 to 2010).
- Familial Search Subcommittee of the Virginia Scientific Advisory Committee, Chair (2006 to 2007).
- Y-STR Validation Subcommittee of the Virginia Scientific Advisory Committee, Chair (2008).
- Ohio Board of Regents Faculty Credentials Committee (co-chair), (2012).
- Participant, Expert meeting for the US General Accountability Office's study of forensic algorithms, facilitated by the US National Academy of Science's Computer Science and Telecommunications Board (2020).
- Member, US National Institute of Standards and Technology's Organization of Scientific Area Committee (OSAC) for Forensic Science Scientific and Technical Review Panel for the OSAC Proposed Standard "Standards for Setting Analytical and Stochastic Thresholds for Application to Forensic DNA Casework Using Electrophoresis Platforms." (2020-2021).
- NASA iTech Pitch Competition Judge (2019-2023).
- Penn State University Eberly College of Science Pitch Competition Mentor and Judge (2021-present).
- Ohio Department of Higher Education PITCHX Competition Selection Panel Member (2021-2023).
- Ohio Area 8 Workforce Development Board, Member (2019-2022).
- Intra-University Council Regional Dean Council, Member (2019-2022).
- Mercer County (OH) Chamber of Commerce, Member (2019-2022).
- Greene County (OH) CATS Transit Board, Member (2022-present).
- Precinct Judge/Voting Location Manager, Greene County, Ohio, Board of Elections (2022-present).

Administrative responsibilities:

- Faculty advisor, Wright State University Biological Sciences Association. (1994 to 2002; 2023 to present).
- Organizer and co-founder, Wright State University Molecular Biology Retreat. (1995 to 2003).
- Chapter president, Sigma Xi (National Scientific Honor Society). (1997 to 2001).
- Associate director's board member, The Engineers' Club of Dayton. (1997 to 2001).
- Board of Directors, Chairman, Forensic Bioinformatic Services, Inc. (2002 to present).
- Special Assistant for Completion Initiatives, Executive on-loan to administer the \$470,000 Bridges to Success Initiative. Ohio Department of Higher Education, (2016 to 2017).

Administrative responsibilities (continued):

Entrepreneur-in-Residence, Ohio Department of Higher Education, (2019 to present).

Interim Dean and Chief Administrative Officer, Wright State University, Lake Campus (2019-2022).

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 378 of 739 PageID

EXHIBIT 18A

Dr. Istvan Albert Research Professor of Bioinformatics Pennsylvania State University

Life Sciences Building, MSC 206C, University Park 16801, PA

Email: iua1@psu.edu
Web: https://www.ialbert.me

Professional Training

Stanford University, CA, USA	Bioinformatics Certificate	2004
University of Notre Dame, IN, USA	Ph.D. Physics	2001
Babes-Bolyai University, CL, RO	M.Sc. Physics	1996
Babes-Bolyai University, CL, RO	B.Sc. Physics	1995

Industry Certifications

IBM Corporation, USA	Certified XML Developer	2002
SUN Microsystems, USA	Certified Java Programmer	2003

Positions and Employment

2015 – present	Research Professor of Bioinformatics, Biochemistry and Molecular Biology, Pennsylvania State University
2009 – present	Director of the Bioinformatics Consulting Center, Pennsylvania State University,
2015 – 2020	Director of the Online Graduate Certificate in Applied Bioinformatics, Pennsylvania State University,
2010 – 2015	Research Associate Professor of Bioinformatics, Biochemistry and Molecular Biology, Pennsylvania State University
2006 – 2010	Research Assistant Professor of Bioinformatics, Biochemistry and Molecular Biology, Pennsylvania State University
2003 – 2006	Research Associate, Huck Institutes for the Life Sciences, Pennsylvania State University
2001 - 2003	Staff Scientist, Department of Computer Science, University of Minnesota
1996 - 2001	Research Assistant, Department of Physics, University of Notre Dame

Notable accomplishments

- Author of the Biostar Handbook, a comprehensive and practical introduction into Bioinformatics.
 https://www.biostarhandbook.com/ The book has been adopted into bioinformatics curricula across the world.
- Program director of the online graduate certificate program Applied Bioinformatics, offered by the Penn State World Campus between 2015 and 2020. Since launching the program, we have enrolled over 150 full-tuition students.
- Lead developer of BioStar: An Online Question & Answer Resource for the Bioinformatics
 Community: http://www.biostars.org. Since 2010, it has become the world's most widely accessed bioinformatics resource. As of today, the site is visited by over 2 million unique users per year, generating over a million page views per month.
- Director of the Bioinformatics Consulting Center at Penn State. This organization, proposed and deployed under my supervision, aims to create bioinformatics support services targeted at scientists affiliated with Penn State. We have helped faculty secure research funding from individual grants to large-scale efforts of over \$30 million.

Skills:

- Over ten years of experience with high dimensionality data analysis, genomic data, and visualization.
- Over ten years of experience training students, scientists, and non-technical participants.
- Successful in securing funding from governmental and private agencies.
- Well-versed in applications of genomics in science.
- Published more than 70 peer-reviewed scientific works.
- Served as a scientific expert in high-profile legal cases.

Teaching Experience

- Course instructor for BMMB 852, Applied Bioinformatics. I have developed a new course that covers scientific computing and bioinformatics education for life scientists. The course started as a special topics course, and within two years, it has been adopted as a required course for the Bioinformatics and Genomics Ph.D. program. In 2014, I was awarded the Paul M. Althouse Outstanding Teaching Award.
- Under my initiative and leadership, Penn State launched the Applied Bioinformatics Online
 Graduate Certificate offered via the Penn State World Campus. I was the program director for this
 effort, coordinating the work necessary to launch a certificate requiring the completion of 4 different
 courses.

Supervisory roles

- Currently supervising a full-time staff member in the position of Bioinformatics Research Associate.
- Served on the Ph.D. and M.Sc. committees of over twenty students.
- Advising and meeting regularly with dozens of PIs, postdoctoral researchers, and graduate students from various departments. In the past year alone, we have assisted over twenty research groups with their data analysis needs.

Advisory roles

I have advised many students in both official and unofficial capacities. A subset of these individuals includes:

- Aswathy Sebastian, Thesis Advisor (2018-2024)
- Siddarth Wekhande, Master's Thesis Committee Member (2018 2019).
- Natay Aberra, Staff Researcher, (2017-2020).
- Ed Provencher, Ph.D. Dissertation Committee Member (2020 present).
- Taejun Chun, Ph.D. Dissertation Committee Member (2019 present).
- Mitchel Goodwin, Ph.D. Dissertation Committee Member (2020 present).
- Stephanie Collins, Ph.D. Dissertation Committee Member (2018 2023).
- Emily Van Syock, Ph.D. Dissertation Committee Member (2018 2023).
- Emma Rose, Ph.D. Dissertation Committee Member (2018 2023).
- Laura Jimenez, Master. Dissertation Committee Member (2018 2022).
- Nabeel Ahmed, Penn State, Ph.D. Dissertation Committee Member (2015 2019).
- Ana Maria Gonzales, Penn State, Ph.D. Dissertation Committee Member (2015 2019).
- Balaji Kumar, Penn State, Ph.D. Dissertation Committee Member (2019 2021).
- Zachary Mandell, Penn State, Ph.D. Dissertation Committee Member (2019 2022).
- Robert Nichols, Penn State, Ph.D. Dissertation Committee Member (2015 October 2, 2019).
- Ben Niu, PSU, Ph.D. Dissertation Committee Member (January 1, 2013 December 31, 2018).
- Utsav Pandey, PUS, Ph.D. Dissertation Committee Member (January 1, 2013 December 31, 2018).
- Sartok Rahman, Penn State, Ph.D. Dissertation Committee Member (2019 Present).
- Eric Wafula, Penn State, Ph.D. Dissertation Committee Member (2016 2019).
- Yinan Wan, Master's Thesis Advisor (2010-2014)

I serve on about 4-5 Ph.D student committees each academic year.

Academic Service

- Served as a referee on over 70 scientific papers in Physics, Computer Science, and Bioinformatics.
- Served as a grant reviewer for various scientific organizations both in the US and internationally.
- Actively involved in the admission process of Penn State Bioinformatics and Genomics Ph.D. programs. I interview and evaluate a large number of students each year.
- Active participant on the Biostar website, created over 3000 posts imparting advice to newcomers to this field.

List of Publications

I have published in three distinct scientific fields: **Physics**, **Computer Science**, and **Life Sciences**. In each of these fields, I have co-authored works published in the *most highly rated and selective journals* or conferences of that scientific domain: *Physical Review Letters*, *Conference on Human Factors in Computing Systems*, *Bioinformatics*, *Genome Research*, and *Nature*.

- 1. Albert, I. (2024). GeneScape: A Python package for gene ontology visualization. *Journal of Open Source Software* 9(98), 6624. DOI: 10.21105/joss.06624 https://doi.org/10.21105/joss.06624
- 2. Zeng, H., Ali, S., Sebastian, A., Ramos-Medero, A. S., Albert, I. (Author), Dean, C., & Liu, A. (2024). CPLANE protein INTU regulates growth and patterning of the mouse lungs through cilia-dependent Hh signaling. *Developmental biology* 515, 92--101.
- 3. Laurel R Seemiller, Lisa R Goldberg, Aswathy Sebastian, Sue Rutherford Siegel, Craig Praul, Dana Zeid, Istvan Albert, Jacob Beierle, Camron D Bryant, Thomas J Gould, Alcohol and fear conditioning

- produce strain-specific changes in the dorsal hippocampal transcriptome of adolescent C57BL/6J and DBA/2J mice, *Alcohol: Clinical and Experimental Research*, (2024)
- 4. Lauren N McKinley, McCauley O Meyer, Aswathy Sebastian, Benjamin K Chang, Kyle J Messina, Istvan Albert, Philip C Bevilacqua; Direct testing of natural twister ribozymes from over a thousand organisms reveals a broad tolerance for structural imperfections, *Nucleic Acids Research*, (2024)
- 5. Kulkarni, S., Morrissey, A., Sebastian, A., Keller, C. A., Giardine, B., Smith, C., Akinniyi, O. T., Arnaoutov, A., Albert, I. (Author), Mahony, S., & others (2024). Human CCR4-NOT is a global regulator of gene expression and is a novel silencer of retrotransposon activation. *bioRxiv*, 2024--09
- 6. Godin, Mitchell J; Sebastian, Aswathy; Albert, Istvan; Lindner, Scott E; Long-Read Genome Assembly and Gene Model Annotations for the Rodent Malaria Parasite Plasmodium yoelii 17XNL *Journal of Biological Chemistry 299 (7) (2023)*
- 7. Misra, Sougat; Lee, Tai-Jung; Sebastian, Aswathy; McGuigan, John; Liao, Chang; Koo, Imhoi; Patterson, Andrew D; Rossi, Randall M; Hall, Molly A; Albert, Istvan; Loss of selenoprotein W in murine macrophages alters the hierarchy of selenoprotein expression, redox tone, and mitochondrial functions during inflammation *Redox Biology* (2023)
- 8. Bellfy, Lauren; Smies, Chad W; Bernhardt, Alicia R; Bodinayake, Kasuni K; Sebastian, Aswathy; Stuart, Emily M; Wright, Destiny S; Lo, Chen-Yu; Murakami, Shoko; Boyd, Hannah M; The clock gene Per1 may exert diurnal control over hippocampal memory consolidation *Neuropsychopharmacology* (2023)
- 9. Piperaquine-resistant PfCRT mutations differentially impact drug transport, hemoglobin catabolism and parasite physiology in Plasmodium falciparum asexual blood stages
 John Okombo, Sachel Mok, Tarrick Qahash, Tomas Yeo, Jade Bath, Lindsey M Orchard, Edward Owens, Imhoi Koo, Istvan Albert, Manuel Llinás, David A Fidock *PLoS pathogens 18 (10), (2022)*
- Chai, Zhi; Lyu, Yafei; Chen, Qiuyan; Wei, Cheng-Hsin; Snyder, Lindsay M; Weaver, Veronika; Sebastian, Aswathy; Albert, István; Li, Qunhua; Cantorna, Margherita T; RNAseq studies reveal distinct transcriptional response to vitamin A deficiency in small intestine versus colon, uncovering novel vitamin A-regulated genes The Journal of nutritional biochemistry (2022)
- 11. Kamens, Helen M; Miller, Carley N; Caulfield, Jasmine I; Zeid, Dana; Horton, William J; Silva, Constanza P; Sebastian, Aswathy; Albert, Istvan; Gould, Thomas J; Fishbein, Diana; Adolescent stress reduces adult morphine-induced behavioral sensitization in C57BL/6J mice *Frontiers in Behavioral Neuroscience* 15 (2022)
- 12. Saini, Mohit Kumar; Sebastian, Aswathy; Shirotori, Yoshiki; Soulier, Nathan T; Garcia Costas, Amaya M; Drautz-Moses, Daniela I; Schuster, Stephan C; Albert, Istvan; Haruta, Shin; Hanada, Satoshi; Genomic and Phenotypic Characterization of Chloracidobacterium Isolates Provides Evidence for Multiple Species Frontiers in Microbiology (2022)
- 13. Lin, Yishan; Grembi, Jessica A; Goots, Sara S; Sebastian, Aswathy; Albert, István; Brennan, Rachel A; Advantageous microbial community development and improved performance of pilot-scale field systems treating high-risk acid mine drainage with crab shell Journal of Hazardous Materials (2022)
- 14. Saini, Mohit Kumar; Yoshida, Shohei; Sebastian, Aswathy; Hara, Eri; Tamaki, Hideyuki; Soulier, Nathan T; Albert, Istvan; Hanada, Satoshi; Tank, Marcus; Bryant, Donald A; Elioraea tepida, sp. nov., a Moderately Thermophilic Aerobic Anoxygenic Phototrophic Bacterium Isolated from the Mat Community of an Alkaline Siliceous Hot Spring in Yellowstone National Park, WY, USA *Microorganisms* (2022)

- 15. Lindner, Scott E; Swearingen, Kristian E; Shears, Melanie J; Sebastian, Aswathy; Walker, Michael P; Vrana, Erin N; Hart, Kevin J; Minns, Allen M; Albert, Istvan; Sinnis, Photini; Addendum: Transcriptomics and proteomics reveal two waves of translational repression during the maturation of malaria parasite sporozoites *Nature communications* 13 (2022)
- 16. Chai, Zhi; Lyu, Yafei; Chen, Qiuyan; Wei, Cheng-Hsin; Snyder, Lindsay M; Weaver, Veronika; Sebastian, Aswathy; Albert, István; Li, Qunhua; Cantorna, Margherita T; Transcriptional Profiling of the Small Intestine and the Colon Reveals Modulation of Gut Infection with Citrobacter rodentium According to the Vitamin A Status *Nutrients* (2022)
- 17. Rufai, S. B., McIntosh, F., Poojary, I., Chothe, S., Sebastian, A., Albert, I. (Author), Praul, C. A., Venkatesan, M., Mahata, G., Maity, H., Dandapat, P., Michael, J. S., Katani, R., Kapur, V., & Behr, M. A. (2021). Complete Genome Sequence of Mycobacterium orygis Strain 51145. *Microbiology resource announcements*, 10(1).
- 18. Goldberg, L., Zeid, D., Kutlu, M. G., Cole, R. D., Lallai, V., Sebastian, A., Albert, I. (Author), Fowler, C., Parikh, V., & Gould, T. (2021). Paternal nicotine enhances fear memory, reduces nicotine administration, and alters hippocampal genetic and neural function in offspring. *Addiction biology*, 26(1), e12859. ISBN/ISSN #/Case #/DOI #: 1355-6215
- 19. Ford, S. A., Albert, I. (Author), Allen, S. L., Chenoweth, S. F., Jones, M. J., Koh, C., Sebastian, A., Sigle, L. T., & Mcgraw, E. (2020). Artificial selection finds new hypotheses for the mechanism of Wolbachia-mediated dengue blocking in mosquitoes. *Frontiers in microbiology*, 11, 1456.
- 20. Saini, M. K., ChihChe, W., Soulier, N., Sebastian, A., Albert, I. (Author), Thiel, V., Bryant, D. A., Hanada, S., & Tank, M. (2020). Caldichromatium japonicum gen. nov., sp. nov., a novel thermophilic phototrophic purple sulfur bacterium of the Chromatiaceae isolated from Nakabusa hot springs, Japan. *International journal of systematic and evolutionary microbiology*, 70(11), 5701--5710.
- 21. Rosenthal, E. R., Sebastian, A., Potnis, N., Albert, I. (Author), & Bull, C. (2020). Comparative genomic analysis of the lettuce bacterial leaf spot pathogen. *Plant Health 2020 Online*.
- 22. Aberra, N., Sebastian, A., Maloy, A. P., Rees, C. B., Bartron, M. L., & Albert, I. (Author) (2020). Bioinformatics recipes: creating, executing and distributing reproducible data analysis workflows. *BMC Bioinformatics*, 21(1), 292.
- 23. Yeh, Y.-T., Gulino, K., Zhang, Y., Sabestien, A., Chou, T. W., Zhou, B., Lin, Z., Albert, I. (Author), Lu, H., Swaminathan, V., Ghedin, E., & Terrones Maldonado, M. (2020). A rapid and label-free platform for virus capture and identification from clinical samples. *Proceedings of the National Academy of Sciences of the United States of America*. 117(2), 895-901.
- 24. Ford, S., Allen, S. D., Sebastian, A., Albert, I. (Author), Chenoweth, S., & Mcgraw, E. (2019). Using Evolutionary Approaches to Dissect the Genetic Basis of Wolbachia-Mediated Blocking of Dengue Virus in Aedes Aegypti. *American Journal of Tropical Medicine and Hygiene, 101*, 386--386.
- 25. Goldberg, L., Zeid, D., Kutlu, M. G., Cole, R. D., Lallai, V., Sebastian, A., Albert, I. (Author), Fowler, C. D., Parikh, V., & Gould, T. (2019). Paternal nicotine enhances fear memory, reduces nicotine administration, and alters hippocampal genetic and neural function in offspring. *Addiction biology*, e12859
- 26. Ford, S. A., Allen, S., Ohm, J. R., Sigle, L. T., Sebastian, A., Albert, I. (Author), Chenoweth, S. F., & Mcgraw, E. (2019). Selection on Aedes aegypti alters Wolbachia-mediated dengue virus blocking and fitness. *Nature Microbiology, 4*(11), 1832-1839.

- 27. Horton, W. J., Jensen, M., Sebastian, A., Praul, C. A., Albert, I. (Author), & Bartell, P. A. (2019). Transcriptome Analyses of Heart and Liver Reveal Novel Pathways for Regulating Songbird Migration. *Scientific reports*, *9*(1), 6058.
- 28. Chothe, S. K., Sebastian, A., Thomas, A., Nissly, R., Byukusenge, M., Wolfgang, D. R., Mor, S. K., Goyal, S., Albert, I. (Author), Jayarao, B. M., & others (2018). Whole-Genome Sequences of 18 Bovine Alphaherpesvirus 1 Field Isolates from Pennsylvania and Minnesota. *Genome Announcements*, 6(17), e00294--18.
- 29. Liang, X., Hart, K. J., Dong, G., Siddiqui, F. A., Sebastian, A., Li, X., Albert, I. (Author), Miao, J., Lindner, S., & Cui, L. (2018). Puf3 participates in ribosomal biogenesis in malaria parasites. *J Cell Sci*, jcs--212597.
- 30. Niu, B., Coslo, D. M., Bataille, A., Albert, I. (Author), Pugh, B. F., & Omiecinski, C. J. (2018). In vivo genome-wide binding interactions of mouse and human constitutive androstane receptors reveal novel gene targets. *Nucleic acids research*, *46*(16), 8385-8403.
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Conference Proceedings

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- 3. Miller, B. N., Albert, I. (Author), Lam, S. K., Konstan, J. A., & Riedl, J. (2003). MovieLens unplugged: experiences with an occasionally connected recommender system. *Proceedings of the 8th international conference on Intelligent user interfaces.* (pp. 263--266).
- 4. McNee, S. M., Albert, I. (Author), Cosley, D., Gopalkrishnan, P., Lam, S. K., Rashid, A. M., Konstan, J. A., & Riedl, J. (2002). On the recommending of citations for research papers. *Proceedings of the 2002 ACM conference on Computer supported cooperative work.* (pp. 116--125).
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- Lipid nanoprobe integrated microdevice for extracellular vesicle isolation and duplex sequencing-based mutation detection for non-invasive lung cancer diagnosis, funded by National Cancer Institute, \$488,116
- 2. Computation, Bioinformatics, and Statistics (CBIOS) Training Program Renewal, funded by National Institute of General Medical Sciences, \$316,906.
- 3. Development of automated tools and databases useful for genetic data reduction and analysis, funded by U.S. Fish and Wildlife Service, \$65,000.
- 4. Environmental Ah Receptor Ligand Impact on the Host-Microbiome Metabolic Axis, funded by National Institute of Environmental Health Sciences, \$344,694; 157, 200.
- 5. Development of a bioinformatic pipeline and other analysis tools for DNA metabarcode data, funded by U.S. Fish and Wildlife Services, \$45,0000.
- 6. Vitamin D Fluctuations and the Mucosal Immune Response Year 8, funded by National Center for Complementary and Integrative Health, \$300,000.
- 7. Temporal Genomics Mechanisms Underlying Disease and Aging, funded by National Institute on Aging, \$237,900.
- 8. Development of a bioinformatic pipeline and other analysis tools for DNA metabarcode data, funded by U.S. Fish and Wildlife Service, \$98,909.
- 9. Global Health, Emerging Infectious Diseases, and Food Safety Implications of Bushmeat Consumption, funded by Defense Threat Reduction Agency, \$776,902.
- 10. Environmental Ah Receptor Ligand Impact on the Host-Microbiome Metabolic Axis, National Institute of Health \$256,634
- 11. Transcriptomes and Proteomes of Plasmodium Vivax, funded by National Institute of Allergy and Infectious Diseases, \$169,726.
- 12. Targeting Dynamics of CAR and PXR in the Mouse and Human Genomes, funded by National Institute of General Medical Sciences, \$37, 375.
- 13. FXR and the Gut Microbiota as Modulators of Obesity (TSF 14/15), funded by PA Tobacco Settlement Fund, \$167,410.
- 14. Damage mitigation in signal transduction networks, funded by National Science Foundation, \$164,065.
- 15. Transcriptones and Preteomes of Plasmodium Vivax, funded by National Institute of Allergy and Infectious Diseases, \$216, 632.
- 16. Broccoli-mediates functional changes in the gut microbiome, funded by USDA National Institute of Food and Agriculture, \$447,790.
- 17. Vitamin A mediated protection from gastrointestinal infection, funded by National Institute of Allergy and Infectious Diseases, \$476,920.
- 18. Southeast Asia Malaria Research Center Supplement, funded by National Institute of Allergy and Infectious Diseases, \$189,143.
- 19. MRI: Acquisition of an Illumina HiSeq2000 as a core sequencing instrument for genomics and gene expression research, National Science Foundation, \$569,419.

- 20. Sex-specific gene expression in malaria parasite Plasmodium falciparum, funded by Institute of Allergy and Infectious Diseases, \$223,500.
- 21. High resolution mapping of function elements in the yeast genome (Principal Investigator: Pugh, Benjamin F.), funded by National Human Genome Research Institute, \$350,000.
- 22. Penn State Clinical and Translational Science Institute (Co-Principal Investigators: McHale, Susan M., Kris-Etherton, Penny M., Vanden Heuvel, John P., Aronson, Keith R., Miller, Webb C., Slavkovic, Aleksandra B., Marks, Jonathan H., Chow, Mosuk, West, Sheila G., Nembhard, Harriet B., Pawelczyk, James A., funded by National Center for Research Resources, \$4,457,207.
- 23. Tailoring genomic data to the needs of experimental biologists and educators (Principal Investigator: Nekrutenko, Anton), funded by National Science Foundation, \$234,556.
- 24. A computational platform for merging genomics and molecular evolution (Principal Investigator: Nekrutenko, Anton), funded by National Science Foundation, \$261,385
- 25. Bioinformatics Consulting Center at University Park and Hershey Medical Center, Phase II (TSF) (Principal Investigator: Rosenberger, James, L.), funded by PA Tobacco Settlement Fund, \$82,554.

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 391 of 739 PageID

EXHIBIT 18B

Michael L. Metzker

(last updated April 24, 2025)

I. General Biographical Information

a. Personal:

Home address: 12015 Surrey Lane, Houston, TX 77024

Date of birth: September 20, 1962

United States Citizenship:

b. Education:

1984 University of California — Davis, Davis, CA

B.S. — Biochemistry & Biophysics

1996 Baylor College of Medicine, Houston, TX

Ph.D. — Molecular & Human Genetics

c. Academic Appointments:

The second of th	
2014-to-2019	Adjunct Associate Professor, Department of Molecular & Human
	Genetics & Human Genome Sequencing Center,
	Baylor College of Medicine, Houston, TX
2009-to-2019	Adjunct Associate Professor, Department of Chemistry,
	Rice University, Houston, TX
2009-to-2014	Associate Professor, Department of Molecular & Human Genetics &
	Human Genome Sequencing Center,
	Baylor College of Medicine, Houston, TX
2009-to-2014	Adjunct Associate Professor, Cell & Molecular Biology,
	Baylor College of Medicine, Houston, TX
2001-to-2008	Adjunct Assistant Professor, Department of Chemistry,
	Rice University, Houston, TX
2000-to-2008	Adjunct Assistant Professor, Cell & Molecular Biology,
	Baylor College of Medicine, Houston, TX
1999-to-2008	Assistant Professor, Department of Molecular & Human Genetics &
	Human Genome Sequencing Center,
	Baylor College of Medicine, Houston, TX
	2009-to-2019 2009-to-2014 2009-to-2014 2001-to-2008 2000-to-2008

d. Corporate positions and other professional experiences:

•	·
2013-to-Present	Founder, President & CEO, RedVault Biosciences, Houston TX
2022-to-2023	Co-founder & CTO, 454 Bio, Inc.
2012	Founder, CTO, LaserGen, Inc.
2010	Consulted with Law & Order SVU on the episode, The Quickie
2009	Appeared on ABC's 20/20 profiling Collin Co. HIV criminal case
2009	Collin Co. work appeared on Oprah
2007-to-2009	Expert witness for HIV criminal case, Collins Co., TX
2004	Expert witness for HIV criminal case, Thurston Co., WA

2003	Appeared on truTV's series Forensics Files in episode #152,
	"Shot of Vengeance"
2002-to-2012	Founder, President & CEO, LaserGen, Inc., Houston TX
1997-to-1999	Expert witness for HIV criminal case, Lafayette, LA
1996-to-1999	Senior Research Biologist, Merck Research Laboratories, West Point, PA
1987-to-1991	Associate Scientist, Applied Biosystems, Inc. (ABI), Foster City, CA
1984-to-1987	Research Chemist, Bio-Rad Laboratories; Richmond, CA
1983-to-1984	Laboratory Technician, Aerojet-General Corporation; Sacramento, CA

e. Prior Expert Experience

In the past five years, I have provided expert testimony at a Markman hearing, trial or deposition in the following cases:

- Plexxikon, Inc. v. Novartis Pharmaceuticals Corp., 4:17-cv-04405-HSG (EDL; on behalf of Plexxikon, Inc.)
- Guardant Health, Inc. v. Foundation Medicine, Inc. CA No. 17-1616 (LPS) (CJB, on behalf of Foundation Medicine, Inc.)
- ArcherDx, Inc. v. Qiagen Inc. CA 18-cv-01019-MN-CJB (on behalf of Qiagen)
- Illumina, Inc. v. Natera, Inc. CA 3:18-cv-1662-SI (on behalf of Natera)
- Illumina, Inc v. Complete Genomics, Inc. Case No. 20-cv-1465 (on behalf of Complete Genomics)
- Complete Genomics, Inc. v. Illumina, Inc & Illumina Cambridge, LTD. Case No. 19-970-MN (on behalf of Complete Genomics)
- Pillar Biosciences, Inc. v. Swift Biosciences, Inc. Case No. IPR2021-00401 (on behalf of Swift Biosciences)
- Ravgen, Inc. v. Ariosa Diagnostics, Inc.; Roche Sequencing Solutions, Inc.; Roche Molecular Systems, Inc. (collectively "Roche") Case No. 20-cv-1646 (on behalf of Roche)
- Illumina Cambridge Limited and Illumina Singapore Pte Limited ("Illumina") v. Comercial Rafer, S.L. and MGI Latvia Tech, SIA ("MGI"), Commercial Court of Barcelona, Spain, matter 249.1.4 1249/2020-3 (on behalf of MGI)
- Guardant Health, Inc. v. Natera, Inc., Case No. 3:21-cv-04062 (on behalf of Natera)
- DNA Genotek, Inc. v. Spectrum Solutions, Case No. 21-cv-0516 (on behalf of DNA Genotek
- Twinstrand Biosciences, Inc v. Guardant Health, Inc.., Case No. 1:21-cv-01126 (on behalf of Twinstrand Biosciences)
- The Trustees of the University of Pennsylvania and Regenxbio, Inc. v. Sarepta Therapeutics and Sarepta Therapeutics Three, Inc, Case No. 20-1226 (on behalf of The Trustees of the University of Pennsylvania and Regenxbio, Inc)
- Spectrum Solutions v. DNA Genotek, Inc., Inter Partes Review IPR2022-01347 (on behalf of DNA Genotek

- Invitae Corp. v. Natera, Inc.; Case No. 1:21-cv-006699-LPS and 1:21-cv-01635-LPS, (on behalf of Natera); US District Court, District of Delaware
- Natera, Inc., v. Neogenomics Laboratories, Inc., Case No. 1:23-cv-629 (on behalf of Natera)
- 10x Genomics, Inc. & Harvard College v. Vizgen, Inc., Case No. 22-595-MFK (on behalf of Vizgen)

II. Research Information

a. Research Support

1 — Pending research support:

Technical description: RedVault proposes development of a low cost, rapid, and accurate POC assay for the detection of syphilis, chlamydia, and/or gonorrhea that could facilitate early detection, thus potentially reducing transmission and sequelae as well as improve therapeutic outcomes in the clinic.

Funding agency: NIH

Investigator relationship: PI: Michael Metzker *Proposed date of funding:* 09/30/2025–09/29/2026

Annual costs: \$308,803

Grant: Not assigned yet, titled, "Detection of small RNAs from urine samples of patients infected with syphilis, chlamydia, and/or gonorrhea using a single POC, multiplex target reporter construct (TRC) assay by lateral flow."

2 — Completed research support:

Technical description: RedVault proposes development of a low cost, rapid, and accurate POC assay for the detection of chlamydia and gonorrhea that could facilitate early detection, thus potentially reducing transmission and sequelae as well as improve therapeutic outcomes in the clinic.

Funding agency: CDC

Investigator relationship: PI: Michael Metzker

Date of funding: 09/30/2023-03/31/2025

Annual costs: \$299,928

Grant: 1R43PS005272-01-00, titled, "POC detection of chlamydia and gonorrhea small RNAs

using a target reporter construct assay by lateral flow in urine surrogates."

Technical description: RedVault proposed the study and sequencing of genomes that has led to amazing discoveries in forensics, history, and medicine. Previous methods associated with preparing a DNA sample for sequencing depend on computationally reconstructing small pieces of data to understand genomic structure and variations, which is time intensive, error prone, and not accurate enough for large scale genomic information. The research proposed here is oriented toward significantly improving the methods of sample preparation, which will lead to improved efficiency, accuracy, and reduced costs to sequence DNA, thereby making the technology more accessible to more people.

Funding agency: NIH/NCI

Investigator relationship: PI: Michael Metzker *Date of funding:* 02/01/2019 – 04/31/2023

Annual costs: \$224,998

Grant: R43 CA232896-01A1, titled "Solid-phase replication of long template libraries for next-generation sequencing"

Technical description: RedVault Biosciences' proposes an innovative approach to reliably interrogate plasma specimens for clinically relevant miRNAs. Successful development of this technology may deliver a fundamental advancement in the cancer screening, tumor surveillance, and miRNA research fields.

Funding agency: NIH/NCI

Investigator relationship: PI: Michael Metzker *Date of funding*: 06/07/2016 – 03/06/2018

Annual costs: \$199,859

Grant: R43 CA200398-01A1, titled, "Digital Analysis of Plasma miRNA populations in Pancreatic

Cancer."

Technical description: RedVault Biosciences' proposal here is oriented toward significantly improving the methods of sample preparation, which will lead to improved efficiency, accuracy, and reduced costs to sequence DNA.

Funding agency: NIH/NCI

Investigator relationship: PI: Michael Metzker *Date of funding:* 01/14/2016 – 02/13/2017

Annual costs: \$146,801

Grant: R43 CA196134-01A1, titled, "Efficient Creation of Long-Template Libraries for Next-

Generation Sequencing"

Technical description: The major goals of this project are to support sequencing and technology development in the areas of human genetics, cancer, the microbiome and comparative genomics.

Funding agency: NIH/NHGRI

Investigator relationship: Richard A. Gibbs; Co-Director Boerwinkle; co-PIs Muzny, Wheeler,

Metzker, Worley

Date of funding: 11/01/2011 - 02/08/2015; effective end 02/08/14

Annual costs: \$20,119,270

Grant: U54 HG003273-09, titled, "The Human Genome Sequencing Center"

Technical description: This proposal represents a request for continued funding of the Mayo Clinic Pharmacogenomics Research Network (PGRN) grant, "Pharmacogenetics of Phase II Drug Metabolizing Enzymes." The Mayo PGRN is an integrated, multidisciplinary, pharmacogenomic research effort that is based on a decades-long focus at Mayo on the pharmacogenetics of phase II (conjugating) drug metabolizing enzymes.

Funding agencies: NIGMS, NHLBI, NCI, NIDA, NICHD, NHGRI, NIMH, NIAMS, ORWH Investigator

relationship: Richard Weinshilboum; Co-PIs Gibbs, Metzker, Scherer

Date of funding: 7/01/10 to 06/30/15; effective end 02/08/14

Annual costs: \$425,709

Grant: 2U19GM061388-12, titled "Pharmacogenetics of Phase II Drug Metabolizing Enzymes"

Technical description: This proposal seeks to expand our existing scientific work on HIV forensic studies by developing a robust 'pathogen toolkit' for source identification across a range of biological agents

Funding agencies: National Institute of Justice

Investigator: Michael L. Metzker
Date of funding: 01/01/12 to 12/31/13

Annual costs: \$341,017

Grant: 2011-DN-BX-K534 titled, "Extending the Microbial Forensic Toolkit Through Whole

Genome Sequencing and Statistical Phylogenomics"

Technical description: This Phase I SBIR grant application proposes three aims: (i) identify the most efficient NGS platform by sequencing *E. coli* MG1655 using six platforms, (ii), conduct mixing experiments using purified gram negative and gram positive bacteria using the platform selected in aim (i), and (iii) conduct mixing experiments described in aim (ii) in the presence of human blood to simulate animal wound models.

Funding agency: Office of the Secretary of Defense, Defense Health Program

Investigator relationship: David Hertzog; co-PI Metzker

Date of funding: 02/01/11 to 08/31/12

Annual costs: \$150,000 *Total costs:* \$150,000

Contract: W81XWH-12-C-0061, titled "Feasibility Study to Explore NGS Technologies in

Pathogen Identification"

Technical description: The goal is to evaluate the feasibility of our next-generation, cyclic reversible termination (CRT) sequencing approach by targeting 1,000 candidate genes on

highdensity oligonucleotide chips. Funding agency: NIH: NHGRI

Investigator: Michael L. Metzker

Date of funding: 08/01/08 to 05/31/11

Annual costs: \$230,250 Total costs: \$422,125

Grant: 1R21 HG004757, titled "Targeted CRT Sequencing of 1000 Genes in KPD Patients"

Technical description: The goal is to develop ultrafast sequencing-by-synthesis (SBS) technology

that is practical on a genomic scale. Funding agency: NIH: NHGRI

Investigator: Michael L. Metzker

Date of funding: 10/01/04 to 09/30/08

Annual costs: \$468,575 Total costs: \$2,933,762

Grant: 1 R01 HG003573-01 titled, "Ultrafast SBS Method for large-Scale Human Resequencing"

Technical description: Development of a novel portable DNA sequencer for rapid identification

of single nucleotide polymorphisms (SNPs) in common disease. \\

Funding agency: NIH: NHGRI Investigator: Michael L. Metzker

Date of funding: 06/07/04 to 02/28/06

Grant: 1 R41 HG003265-01 titled, "Development of a Portable PME DNA Sequencer"

Technical description: Development of novel FluoroBase dyes and associated nucleotide triphosphates, which have the potential to create sets of spectrally resolvable dye-terminators. Special note: Originally awarded to Michael L. Metzker as STTR application: Grant converted in

SBIR

Funding agency: NIH:NHGRI

Investigator relationship: Vladislav A. Litosh; co-PI Metzker Date

of funding: 07/11/03 to 12/31/05

Annual costs: \$213,064 Total direct costs: \$289,689

Grant: 1 R43 HG002632-01A1 titled, "Synthesis of FluoroBase Nucleotides for DNA Sequencing"

Technical description: The major goal of this project is to produce a draft sequence of the rhesus macaque and bovine genomes and extract maximal biological information from these data.

Funding agency: NIH: NHGRI

Investigator relationship: Richard A. Gibbs; co-Director Weinstock, co-Pls Muzny, Wheeler,

Metzker, Worley

Date of funding: 11/10/03 to 10/31/06

Annual direct costs: \$21,028,110 Total direct costs: \$89,072,698 Grant: 1 U01 HG02051 titled, "Large Scale Sequencing at BCM-HGSC"

Technical description: The goal of this project is to generate a draft sequence of the genome of

Bos Taurus.

Funding agency: USDA

Investigator relationship: Richard A. Gibbs; co-Director Weinstock, co-Pls Muzny, Wheeler,

Metzker, Worley

Date of funding: 12/01/03 to 11/31/05

Annual direct costs: \$3,879,953 Total direct costs: \$7,853,612 Grant: TEXR-2003-05478 titled, "Bovine Genome Sequencing Project (BGSP)"

Technical description: Development of a novel multi-color fluorescent detection apparatus with potential application for direct detection of targeted regions from genomic DNA materials.

Funding agency: NIH: NHGRI Investigator: Michael L. Metzker Date of funding: 04/01/03 to 03/31/05

Annual costs: \$150,000 Total costs: \$250,000

Grant: 1 R21 HG002443-01A2, titled "Development of Fluorescent Detector for DNA

Sequencing"

Technical description: Development of a novel DNA sequencing strategy by synthesis for

application in high-throughput single nucleotide polymorphism (SNP) analysis.

Funding agency: NIH: NHGRI
Investigator: Michael L. Metzker

Date of funding: 09/30/03 to 03/31/05

Annual costs: \$310,504 *Total costs:* \$436,400

Grant: 1 R41 HG003072-01 titled, "Screening Tag Pol I Variants using 3'-O-Modified-dNTPs"

Technical description: Pilot project to synthesize and characterize modified nucleoside for

potential activity against HIV-1.

Funding agency: Robert A. Welch Foundation

Investigator: Michael L. Metzker

Date of funding: 06/01/01 to 07/31/04

Annual costs: \$50,000 *Total costs:* \$158,000

Grant: Q-1518 titled, "Characterization of HIV-1 drug resistance using 3'-saturated nucleotides"

Technical description: Development of sixteen spectrally-resolved dyes for high-throughput

nucleic acid detection such as DNA sequencing.

Funding agency: NIH: NHGRI

Investigator relationship: Mathew Mahindaratne; co-PI Metzker – special note: Originally awarded to Michael L. Metzker as STTR application and then was converted in SBIR. *Date*

of funding: 07/21/03 to 06/30/05

Annual direct costs: \$214,000 Total direct costs: \$214,000

Grant: 1 R43 HG002567-01A2 titled, "Development of Novel Fluorescent Dyes for DNA

Sequencing"

Technical description: The major goal of this project is to determine the genome sequence of the

rat.

Funding agency: NIH: NHGRI/NHLBI

Investigator relationship: Richard A. Gibbs; co-Director Weinstock, co-Pls Muzny, Wheeler,

Metzker, Worley

Date of funding: 02/27/01 to 02/26/04

Annual direct costs: \$10,976,914 Total direct costs: \$25,950,547 Grant: 1 U54 HG02345-02 titled, "Draft sequence of the rat genome"

Technical description: The major goal of this project is to prepare two types of extremely sensitive fluorescent label "cassettes" for DNA sequencing that may be used with both dye primer and dye

terminator strategies. *Funding agency:* NIH: NHGRI *Investigator relationship:* Kevin Burgess; co-PI Metzker

Date of funding: 09/06/01 to 07/31/05

Annual direct costs: \$38,296 Total direct costs: \$114,923

Grant: Competing Renewal FDN-S80093 titled, "Unnatural nucleotides for DNA sequencing"

Technical description: To develop and validate novel pooling-based methods for the rapid physical

mapping of BAC libraries. Funding agency: NIH: NCRR

Investigator relationship: Aleksandar Milosavljevic; co-PI Metzker Date

of funding: 09/30/02 to 08/31/05

Annual direct costs: \$206,693 Total direct costs: \$612,721

Grant: 1 U01 RR18464-01 titled, "Clone pooling methods for physical mapping"

Technical description: The major goals of this project are extensive mapping and sequencing of

the mouse genome. Funding agency: NIH: NHGRI

Investigator relationship: Richard A. Gibbs; co-Director Weinstock, co-Pls Muzny, Wheeler,

Metzker, Worley

Date of funding: 09/30/99 to 09/30/03

Annual direct costs: \$5,316,551 Total direct costs: \$20,851,198

Grant: 1 U54 HG02139 titled, "Network for large-scale sequencing of the mouse genome"

Technical description: To produce a draft sequence of D. pseudoobscura with annotation and

finishing of selected full-length cDNA and gene-rich regions.

Funding agency: NIH: NHGRI

Investigator relationship: Richard A. Gibbs; co-Director Weinstock, co-PIs Richards, Muzny,

Wheeler, Metzker, Worley

Date of funding: 05/10/02 to 04/30/03

Annual direct costs: \$3,336,210 Total direct costs: \$3,336,210

Grant: 1 U01HG02570 titled, "Sequencing, annotation and assembly of a second Drosophila"

b. National Scientific Participation

1 — Editorial/Advisory Boards:

2003-to-2006	Genome Research, Cold Spring Harbor Laboratory Press
2006-to-2012	Advances in Genome Biology & Technology Meeting, Scientific advisor
2011-to-2013	Genome Canada: Advancing Technology Innovation through Discovery (ATID) Advisory Committee
2 — Review panels:	
Jul 2025	NIH: (DCAI-13): Small Business: Microbial Diagnostics, Detection and Decontamination
Feb 2024	Panel Chair: (SBIR) contract – Topic 108: Development of Rapid POC Diagnostics for Treponema pallidum (Phase II)
Jan 2022	Panel Chair: (SBIR) contract – Topic 108: Development of Rapid POC Diagnostics for Treponema pallidum (Phase I)
Nov 2019	NIH: ZRG1 SBIR/STTR/R21/R03: Infectious disease diagnostics, methods in sterilization & disinfection Study Section panels: IDM-V (12 & 19) NIH: ZRG1 SBIR: Biomaterials, Delivery, and Nanotechnology Study
Jul 2019	Section panel, ZRG1 BST-R (10)
May 2019	Chair, CIHR: Operating Grant CEEHRC (Epigenetics)
Feb 2019	Chair, CIHR: Operating Grant: Epigenetics Clinical Translation
Jan 2018	Invited expert on forensics, Arizona State University
Nov 2017	Chair, CEEHRC Phase II competition, Impact grants
Jul 2017	NASA Translational Research Institute Omics Panel
Mar 2017	CEEHRC Phase II: Platform Centres Renewal; Canadian Institutes of Health Research (CIHR)
Jun 2016	CIHR: Project Grant: Spring 2017 competition
Mar 2016	NIH: Sequencing Technology Special Emphasis Panel, ZHG1 HGR-N (M1)
Jan 2016	Disruptive Innovation in Genomics (DIG) Competition, Genome Canada
Jun 2015	Chair: CIHR's Team Grant: CEEHRC (Epigenetics)
May 2015	Genome Canada Genomics Innovation Network Technology Development International Review Committee
Mar 2015	National Center for Advancing Translational Sciences (NCATS), Special Emphasis Panel
Nov 2014	Genome Canada's Membership to the Genomics Innovation Network and Core Operations Support Funds competition
Oct 2014	Genomics, Computational Biology and Technology (GCAT) study section
Jun 2014	Interdisciplinary Molecular Science and Training – Cell, Molecular, and Computational Biology study section
Mar 2014	Genomics, Computational Biology and Technology (GCAT) study section; Transformative research award review
Feb 2014	ISD study section, Bioengineering Sciences and Technologies

Jan 2014	NASA study section: "Differential Effects on Homozygous Twin Astronauts Associated with Differences in Exposure to Spaceflight Factors"		
Dec 2013	ISD study section, Bioengineering Sciences and Technologies		
May 2013	Partnerships for Enhanced Engagement in Research (PEER) Health, NICHD		
Apr 2013	Terry Fox New Frontiers Program in Cancer Research		
Apr 2013	Science & Technology Innovation Centers' Renewal, Genome Canada		
Jan 2013	Canada-Japan CEEHRC Teams in Epigenetics of Stem Cells, CIHR, Co-chair		
Aug 2012	Chair: Team Grant: CEEHRC - LOI committee.		
Feb 2012	Chair: Epigenomics platform peer review committee, Canadian Institutes		
. 60 2012	of Health research (CIHR)		
Feb 2012	Chair: Epigenetics catalyst peer review committee, CIHR		
Sep 2011	Ad hoc member of NIH Instrumentation and Systems Development (ISD)		
	study section		
Feb 2011	Science & Technology Innovation Center Competition Review: Genome		
	Canada		
Nov 2010	ATID Review: Genome Canada		
Mar 2010	IDDRC P30 REVIEW, ZHD1-MRG-C (ID)		
Oct 2009	Genomics, Computational Biology and technology study section, NIH		
Jul 2009	DP3 Review, ZDK1 GRB-N(01), NIDDK		
Jan 2009	Applied Genomics Research in Bioproducts or Crops (ABC), Genome Canada		
Sep 2008	NCI Structural Biophysics Laboratory Site Visit, NCI		
Nov 2007	Technology Development Competition, Genome Canada		
2005-2007	Permanent member of NIH ISD study section		
Apr 2007	Applied Emerging Technologies for Cancer Research, ZCA1 SRRB-4 (M1), NCI		
Oct 2006	Applied Emerging Technologies for Cancer Research, ZCA1 SRRB-K (J1), NCI		
Jun 2006	Innovative Technologies for the Molecular Analysis of Cancer, ZCA1 SRRBK (O1), NCI		
Mar 2006	Applied Emerging Technologies for Cancer Research, ZCA1 SRRB-9 (M1), NCI		
Oct 2005	ISD study section [ZRG1 ISD (01)], NIBIB		
Oct 2005	Emerging Technologies for Cancer Research, ZCA1 SRRB-4 (J1), NCI		
Jul 2005	ISD study section [ZRG1 ISD (01)], NIBIB		
Jun 2005	Innovative Technologies for Cancer Research, ZCA1 SRRB-3 (O1), NCI		
Mar 2005	ISD study section [ZRG1 ISD (01)], NIBIB		
Mar 2005	Innovative Molecular Analysis Technology, ZCA1 SRRB-C (M2), NCI		
Nov 2004	ISD study section, ZRG1 ISD (01), NIBIB		
Jul 2004	Innovative Molecular Analysis Technology, ZCA1 SRRB-C (01), NCI		
Jul 2004	ISD study section, ZRG1 ISD (01), NIBIB		
Jun 2004	Subcommittee E $-$ Cancer Epidemiology, Prevention & Control study section, NCI-E RPRB (X1), NCI		

Mar 2004	ISD study section, ZRG1 ISD (01), NIBIB
Dec 2003	Genome Technology & Cytogenetics (GT&C) study section, ZRG1 GNM
	(90), NHGRI
Oct 2003	Atopic Dermatitis & Vaccinia Network; Clinical Studies Consortium study
	section [ZAI1 CL-1 (C1), NIAID
Jul 2003	GT&C study section, ZRG1 GNM (90), NHGRI
Nov 2001	Genome study section, CSR-GNM, NHGRI
Jul 2001	Center for Scientific Review – Special Emphasis Panel (CSR-SEP) study
	section [ZRG1 SSS-Y], NHGRI
Jul 2001	Bioengineering Research Partnership study section [ZRG1 SSS-Y (02)],
	NHGRI
Apr 2001	CSR-SEP study section [ZRG1 SSS-Y (11) B], NHGRI
Mar 2001	Microbial Genome Project – study section, DOE
Nov 2000	CSR-SEP SBIR/STTR study section [ZRG1 SSS-Y (10)], NHGRI
Mar 2000	CSR-SEP SBIR/STTR study section [ZRG1 SSS-Y (01)], NHGRI
Nov 1999	CSR-SEP SBIR/STTR study section [ZRG1 SSS-Y (01)], NHGRI
Jul 1999	Technologies for Generation of Full-Length Mammalian cDNA study
	section [CA99-005], NCI
Jul 1999	CSR-SEP SBIR/STTR study section [ZRG1 SSS-Y (01)], NHGRI
Mar 1999	CSR-SEP SBIR/STTR study section [ZRG1 SSS-Y (01)], NHGRI
Mar 1998	SBIR/STTR Molecular Genetics study section [ZRG2 GNM O2B], NHGRI
Mar 1997	Biological & Physiological SEP study section [ZRG2 SSS-Y (15)], NHGRI

3 — Professional societies:

	1996-to-present	American A	Association 1	for t	he Ad	Ivancement of Science
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2000-to-present American Chemical Society
2014-to-present Texas Genetics Society

4 — Invited lectures, presentations, research seminars:

Apr 2016	Critical Path to TB Drug Regimens (CPRT) Workshop, Washington DC, Invited Speaker
May 2015	Advances in Next Generation Sequencing, Online, Keynote speaker
Mar 2013	ABRF- Satellite workshop, Palm Springs, CA; Invited Speaker
Jun 2012	American Society of Microbiology, San Francisco, CA;
	Invited Speaker
Jun 2012	Copenhagenomics, Copenhagen, Denmark, Invited Speaker
Feb 2012	Advances in Genome Biology & Technology, Marco Island, FL;
	Speaker
Apr 2011	Next-Gen Sequencing Conference, Boston, MA; Keynote Speaker
Apr 2011	Texas Association for Clinical Laboratory Science (TACLS), Austin, TX;
	Invited Speaker
Oct 2010	Centre de Regulació Genòmica (CRG) Symposium, Barcelona Spain,
	Invited Speaker
Jun 2010	ACS Meeting, San Diego, CA; Invited Speaker

May 2010	Next Generation Sequencing Workshop, Lübeck University, Germany; Invited Speaker
May 2010	Genomics Automation Conference, Boston, MA; Invited Speaker
Feb 2009	Advances in Genome Biology & Technology, Marco Island, FL
	Invited Speaker
Jun 2008	Workshop on Genotyping-Tissue Expression (GTEx) Resource, NIH
	Invited Participant
Oct 2007	International Conference on Genomics, Shenzhen, China;
	Invited Speaker
Sep 2007	IBC's Discovery-2-Diagnostics Conference, Philadelphia, PA
	Invited Chair & Speaker
Feb 2007	Advances in Genome Biology & Technology, Marco Island, FL
	Invited Speaker
Oct 2006	International Conference on Genomics, Hangzhou, China
	Invited Speaker
Sep 2006	Genomics of Hyperglycaemia, Elsinore, Denmark
	Invited Speaker
Feb 2006	Advances in Genome Biology & Technology, Marco Island, FL
	Invited Speaker
May 2005	5 th Annual RECOMB Satellite meeting on DNA Sequencing Technologies
	and Computation, Stanford University; Invited Speaker
Feb 2005	Advances in Genome Biology & Technology, Marco Island, FL
	Invited Speaker
Feb 2004	Advances in Genome Biology & Technology, Marco Island, FL
	Invited Speaker
Jun 2003	BECON 2003 Symposium on Catalyzing Team Science, NIH
	Invited Speaker
Jan 2002	Agriculture Program Research General Session, Texas A&M University
0 + 2004	Invited Speaker
Oct 2001	Genome sequencing and Analysis Conference XIII, San Diego, CA
Fab 2001	Invited Speaker
Feb 2001	Advances in Genome Biology & Technology, Marco Island, FL
May 2000	Invited Speaker Second Follow-Up Workshop on Priority Setting for Mouse Genomics
May 2000	and Genetics Resources, NIH; Invited Participant
Mar 1009	Full-Length cDNA Cloning: A Workshop on Problems and Solutions, The
Mar 1998	Banbury Center, Cold Spring Harbor; Invited Participant
May 1997	Workshop on Complete cDNA Sequencing, NIH; Invited Participant
ividy 1331	Workshop on Complete CoNA Sequenting, Min, invited Participant

c. Publications

1 — Peer-reviewed articles and reviews:

1. Burgess K, Gibbs RA, **Metzker ML**, and Raghavachari R (1994) Synthesis of an Oxyamide Linked Nucleotide Dimer and Incorporation into Antisense Oligonucleotide Sequences, *J. Chem. Soc., Chem Commun.*, 915-916.

- 2. **Metzker ML**, Raghavachari R, Richards S, Civitello A, Burgess K, and Gibbs RA (1994) Termination of DNA synthesis by novel 3'-modified-deoxyribonucleoside 5'-triphosphates, *Nucleic Acids Res.* 22, 4259-4267.
- 3. **Metzker ML**, Allain KM, and Gibbs RA (1995) Accurate determination of DNA in agarose gels using the novel algorithm *GelScann*(1.0), *Comput. Applic. Biosci.* 11, 187-194.
- 4. **Metzker ML**, Lu J and Gibbs RA (1996) Electrophoretically Uniform Fluorescent Dyes for Automated DNA Sequencing, *Science* 271: 1420-1422.
- 5. Ansari-Lari MA, Liu XM, **Metzker ML**, Rut AR and Gibbs RA (1997) The extent of genetic variation in the CCR5 gene. *Nature Genet*. 16: 221-222.
- 6. Petrukhin K, Koisti MJ, Bakall B, Li W, Xie G, Marknell T, Sandgren O, Forsman K, Holmgren G, Andreasson, S Vujic, M Bergen AAB, McGarty-Dugan V, Figueroa D, Austin CP, **Metzker ML**, Caskey CT, and Wadelius C (1998) Identification of the gene responsible for Best macular dystrophy. *Nature Genet*. 19:241-247.
- 7. **Metzker ML**, Ansari-Lari MA Liu XL, Holder DJ, and Gibbs RA (1998) Quantitation of MixedBase Populations of HIV-1 Variants by Automated DNA Sequencing with BODIPY DyeLabeled Primers. *BioTechniques* 25:446-462.
- 8. Hey PJ, Twells RCJ, Phillips MS, Nakagawa Y, Brown SD, Kawaguchi Y, Cox R, Xie G, Dugan V, Hammond H, **Metzker ML**, Todd JA, and Hess JF (1998) Cloning of a novel member of the low-density lipoprotein receptor family. *Gene* 216:103-111.
- 9. Brown SD, Twells RCJ, Hey PJ, Cox RD, Levy ER, Soderman AR, **Metzker ML**, Caskey CT, Todd JA, and Hess JF (1998) Isolation and characterization of *LRP6*, a novel member of the low density lipoprotein receptor gene family. *Biochem. Biophys. Res. Commun*. 248:879-888.
- 10. **Metzker ML**, Raghavachari R, Burgess K, and Gibbs RA (1998) Elimination of residual natural nucleotides from 3'-*O*-modified-dNTP syntheses by enzymatic Mop-Up. *BioTechniques* 25:814-817.
- 11. Muzny DM, **Metzker ML**, Bouck J, Gorrell JH, Ding Y, Maxim E, and Gibbs RA (1998) Using BODIPY Dye-Primer Chemistry in Large-Scale Sequencing. *IEEE Engineering in Medicine and Biology* 88-93.
- 12. Allikmets R, Seddon JM, Bernstein PS, Hutchinson A, Sharma S, Gerrard B, Li W, **Metzker ML**, Wadelius C, Caskey CT, Dean M, and Petrukhin K (1999) Rare variants of the best disease gene in patients with age-related macular degeneration and other maculopathies. *Hum. Genet.* 104: 449-453.
- 13. Bai C, Connolly B, Liu X, Hilliard CA, Galloway SM, Sandig V, Liu Q, **Metzker ML**, Austin CP, and Caskey CT (2000). Overexpression of a new secreted member of tumor necrosis factor receptor family in gastrointestinal tract tumors. *Proc. Natl. Acad. Sci. USA* 97:1230-1235.
- 14. Sandig V, Youil R, Bett AJ, Franlin LL, Oshima M, Maione D, Wang F, **Metzker ML**, Savino R, Caskey CT (2000) Optimization of the helper-dependent adenovirus system for production and potency *in vivo*. **Proc. Natl. Acad. Sci. USA.** 97:1002-1007.
- 15. Bouck JB, **Metzker ML**, and Gibbs RA (2000) Shotgun sample sequence comparisons between mouse and human genomes. *Nature Genet*. 25:31-3.
- 16. Zhang K, Kniazeva M, Han M, Li W, Yu Z, Yang Z, Li Y, **Metzker ML**, Allikmets R, Zack DJ, Kakuk LE, Lagali PS, Wong PW, MacDonald IM, Sieving PA, Figueroa DJ, Austin CP, Gould RJ, Ayyagari R, and Petrukhin K (2001) A 5-bp deletion in ELOVL4 is associated with two related forms of autosomal dominant macular dystrophy. *Nature Genet.* 27:89-93.
- 17. International Human Genome Sequencing Consortium: Baylor College of Medicine Human Genome Sequencing Center: Gibbs RA, Muzny DM Scherer SE, Bouck JB, Sodergren EJ,

- Worley KC, Rives CM, Gorrell JH, **Metzker ML**, Naylor SL, Kucherlapati RS, Nelson DL, and Weinstock GM (2001) Initial sequencing and analysis of the human genome. *Nature* 409:860-921.
- 18. Twells RC, **Metzker ML**, Brown SD, Cox R, Garey C, Hammond H, Hey PJ, Levy E, Nakagawa Y, Philips MS, Todd JA, and Hess JF. (2001) The sequence and gene characterization of a 400kb candidate region for *IDDM4* on chromosome 11q13. *Genomics* 72:231-242.
- 19. Dederich DA, Okwuonu G, Garner T, Denn A, Sutton A, Escotto M, Martindale A, Delgado O, Muzny DM, Gibbs RA and **Metzker ML** (2002) Glass Bead Purification of Plasmid Template DNA for High-Throughput Sequencing of Mammalian Genomes. *Nucleic Acids Res.* 30:e32
- 20. **Metzker ML**, Mindell DP, Ptak RG, Gibbs RA, and Hillis DM (2002) Molecular Evidence of HIV-1 Transmission in a Louisiana Criminal Case. *Proc. Natl. Acad. Sci. USA* 99:14292-14297.
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- 2. **Metzker ML** and Caskey CT (2001) Polymerase chain reaction. In *Encyclopedia of Life Sciences*. Macmillan References Ltd., London.
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- 4. **Metzker ML** (2006) Emerging Technologies in DNA Sequencing. In *Genomes, Cold Spring Harbor Monograph Series* by HE Sussman and MA Smit (Eds.), Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY.
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- 6. **Metzker ML** and Caskey CT (2009) Polymerase chain reaction. In *Encyclopedia of Life Sciences*. Macmillan References Ltd., London.
- 7. **Metzker ML** (2014) Polymerase chain reaction. *In Discoveries in Modern Science: Exploration, Invention, Technology*. Macmillan References Ltd., London.

3— Posters:

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- Gibbs RA, Richards S, Civitello A, Burgess K, Raghavachari R, Metzker ML (1993) PCT Application No. WO 93/05183. Method and device for rapid DNA or RNA sequencing determination by a base addition sequencing scheme; filed Sep 9, 1991.
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- 4. **Metzker ML** and Gibbs RA (1997) US Patent 5,614,386. Alternative dye-labeled primers for automated DNA sequencing.
- 5. **Metzker ML** and Gibbs RA (1997) PCT Application No. WO 97/00967 Alternative dye-labeled primers, ribonucleotides, deoxyribonucleotides and dideoxyribonucleotides dideoxyribonucleotides for automated DNA analysis and homogeneous amplification/detection assays; filed June 21, 1996.
- 6. **Metzker ML** and Gibbs RA (1998) US Patent 5,728,529. Alternative dye-labeled ribonucleotides, deoxyribonucleotides and dideoxyribonucleotides for automated DNA analysis.
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- 9. **Metzker ML** and Gibbs RA (1999) US Patent 5,994,063. Substituted 4,4 difluoro-4-bora-3A,4A-diaza-s-indacene compounds for homogeneous amplification/ detection assays.
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- 11. Petrukhin K, Caskey CT, Li W, **Metzker ML** (2000) PCT Application No. WO 00/61606. Novel human voltage-gated potassium channel; filed Apr 14, 1999.
- 12. Liu XL, Bai C and **Metzker ML** (2001) PCT Application No. WO 01/42434. DNA molecules encoding human NHL a DNA helicase; filed Dec 9, 1999.
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- 17. Scott GBI, Kittrell C, Curl RF, and **Metzker ML** (2003) PCT Application No. WO 03/021212. Pulsed-multiline excitation for color-blind fluorescence detection; filed Aug 28, 2002.
- 18. Liu XL, Bai C and **Metzker ML** (2004) US Patent 6,762,042. DNA molecules encoding human NHL a DNA helicase.
- 19. Scott GBI, Kittrell C, Curl RF, and **Metzker ML** (2006) US Patent 6,995,841. Pulsed-multiline excitation for color-blind fluorescence detection.
- 20. Petrukhin K, Caskey CT, **Metzker ML**, Wadelius C (2006) US Patent 7,005,290. Best's Macular Dystrophy gene.
- 21. Petrukhin K, Caskey CT, **Metzker ML**, Wadelius C (2006) US Patent Application Publication No. 2006/0105364. Best's Macular Dystrophy gene, filed Sep 27, 2006.
- 22. Petrukhin K, Caskey CT, Li W, **Metzker ML** (2006) European Patent EP 1 173 465 B1. Novel human voltage-gated potassium channel.
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- 24. Todd JA, Hess JW, Caskey CT, Cox RD, Gerhold D, Hammond H, Hey P, Kawaguchi Y, Merriman TR, **Metzker ML**, Nakagawa Y, Phillips MS, Twells RCJ (2007) European Patent EP 0 988 379 B1. LDL-receptor.
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- 26. Liu XL, Bai C and **Metzker ML** (2008) US Patent 7,361,491. DNA molecules encoding human NHL a DNA helicase.
- 27. Scott GBI, Kittrell C, Curl RF, and **Metzker ML** (2009) US Patent 7,511,811. Pulsed-multiline excitation for color-blind fluorescence detection.
- 28. Litosh V, Hersh M, Stupi B, Wu W, **Metzker ML**. PCT Application No. US2009/152353. Nucleotides and nucleosides and methods for their use in DNA sequencing. *Filed*: Jun 11, 2009.
- 29. Wu W, Litosh V, Stupi B, **Metzker ML**. (2011) US Patent 7,893,227. 3'OH unblocked nucleotides and nucleosides, base modified with non-cleavable, terminating groups and methods for their use in DNA sequencing.
- 30. Wu W, Litosh V, Stupi B, **Metzker ML**. (2011) US Patent 7,897,737. 3'OH unblocked nucleotides and nucleosides, base modified with photocleavable, terminating groups and methods for their use in DNA sequencing.
- 31. Wu W, Litosh V, Stupi B, **Metzker ML**. (2011) US Patent 7,964,352. 3'OH unblocked nucleotides and nucleosides, base modified with photocleavable, terminating groups and methods for their use in DNA sequencing.
- 32. Lafferty WM, Beechem J, Hongye S, **Metzker ML** (2011) US Patent Application Publication No. 2011/0311963. Method and Apparatus for Addressable Flow Cells in Single Molecule Sequencing; filed March 16, 2011.
- 33. Lafferty WM, Beechem J, Hongye S, **Metzker ML** (2011) PCT Application No. WO/2011/116120. Method and Apparatus for Addressable Flow Cells in Single Molecule Sequencing; filed March 16, 2011.

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- 35. Litosh V, Stupi B, Hersh M, Wu W, **Metzker ML**. (2012) US Patent 8,148,503. Labeled nucleotides and nucleosides and methods for their use in DNA sequencing.
- 36. Wu W, Litosh V, Stupi B, **Metzker ML**. (2012) US Patent 8,198,029. 3'OH unblocked nucleotides and nucleosides, base modified with non-cleavable, terminating groups and methods for their use in DNA sequencing.
- 37. Wu W, Litosh V, Stupi B, **Metzker ML**. (2013) US Patent 8,361,727. 3'OH unblocked nucleotides and nucleosides, base modified with photocleavable, terminating groups and methods for their use in DNA sequencing.
- 38. Litosh V, Stupi B, Hersh M, Wu W, **Metzker ML**. (2013) US Patent 8,497,360. Nucleotides and nucleosides and methods for their use in DNA sequencing.
- 39. Litosh V, Stupi B, Hersh M, Wu W, **Metzker ML**. (2014) US Patent 8,887,905. Nucleotides and nucleosides and methods for their use in DNA sequencing.
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- 41. Wu W, Litosh V, Stupi B, **Metzker ML**. (2013) US Patent 8,969,535. Photocleavable labeled nucleotides and nucleosides and methods for their use in DNA sequencing.
- 42. Stupi B, Li H, Wu W, Hersh MN, Hertzog D, Morris SE, **Metzker ML**. (2013) PCT Application No. 2013/040257. 5-methoxy 3'-OH Unblocked, fast photocleavable terminating nucleotides and methods for nucleic acid sequencing; filed September 13, 2012.
- 43. Litosh V, Stupi B, Hersh M, Wu W, **Metzker ML**. (2015) US Patent 9,200,319. Nucleotides and nucleosides and methods for their use in DNA sequencing.
- 44. **Metzker ML**, Weier CA (2015) PCT WO2015/157747. Systems and methods for clonal replication and amplification of nucleic acid molecules for genomic and therapeutic applications.
- 45. Stupi B, Li H, Wu W, Hersh MN, Hertzog D, Morris SE, **Metzker ML**. (2016) US Patent 9,399,798. 3'-OH unblocked, fast photocleavable terminating nucleotides and methods for nucleic acid sequencing; to be issued Jul 26, 2016.
- 46. **Metzker ML**, Weier CA (2016) US Patent Application Publication No. 15/122,543. Systems and methods for clonal replication and amplification of nucleic acid molecules for genomic and therapeutic applications; filed Aug 30, 2016.
- 47. Litosh V, Stupi B, Hersh M, Wu W, **Metzker ML**. (2016) European Patent 2 125 856 B1. Photocleavable labeled nucleotides and nucleosides and labeled nucleotides and nucleosides for their use in DNA sequencing.
- 48. Stupi B, Li H, Wu W, Hersh MN, Hertzog D, Morris SE, **Metzker ML**. (2017) US Patent 9,689,035. 3'-OH unblocked, fast photocleavable terminating nucleotides and methods for nucleic acid sequencing.
- 49. **Metzker ML**, Weier CA (2017) PCT Application No. PCT/US2017/036129. Target reporter constructs and uses thereof; filed Jun 6, 2017.
- 50. Stupi B, Li H, Wu W, Hersh MN, Hertzog D, Morris SE, **Metzker ML**. (2017) US Patent 9,689,035. 3'-OH unblocked, fast photocleavable terminating nucleotides and methods for nucleic acid sequencing.
- 51. Litosh V, Stupi B, Hersh M, Wu W, **Metzker ML**. (2017) European Patent 2 307 565 B1. Reversible nucleosides and nucleotides terminators and their use in DNA sequencing.

- 52. Stupi B, Li H, Wu W, Hersh MN, Hertzog D, Morris SE, **Metzker ML**. (2018) US Patent 10,041,115. 3'-OH unblocked, fast photocleavable terminating nucleotides and methods for nucleic acid sequencing.
- 53. Stupi B, Li H, Wu W, Hersh MN, Hertzog D, Morris SE, **Metzker ML**. (2020) European Patent EP 2 755 984 B1. 5-Methoxy. 3'-OH unblocked, fast photocleavable terminating nucleotides and methods for nucleic acid sequencing.
- 54. Stupi B, Li H, Wu W, Hersh MN, Hertzog D, Morris SE, **Metzker ML**. (2021) US Patent 11,001,886. 3'-OH unblocked, fast photocleavable terminating nucleotides and methods for nucleic acid sequencing.
- 55. **Metzker ML**, Weier CA (2021) European Patent EP 3 129 505 B1. Methods for clonal replication and amplification of nucleic acid molecules for genomic and therapeutic applications.
- 56. Stupi B, Li H, Wu W, Hersh MN, Hertzog D, Morris SE, **Metzker ML**. (2021) European Patent EP 3 670 523 B1. 5-Methoxy. 3'-OH unblocked, fast photocleavable terminating nucleotides and their use in methods for nucleic acid sequencing.
- 57. **Metzker ML**, Weier CA (2022) U.S. Patent No. 11,299,769. Target reporter constructs and uses thereof.
- 58. **Metzker ML**, Weier CA (2022) U.S. Patent Application No. 17/702,152. Target reporter constructs and uses thereof, filed Mar 23, 2022.
- 59. **Metzker ML**, Weier CA (2024) European Patent Application EP 4 372 102. Target reporter constructs and uses thereof.

III. Teaching Information:

a. Courses taught at BCM:

2000-to-2018	Molecular Methods: All first-year graduate students are required to		
	take this course. Three lectures taught: cDNA and Genomic Libraries,		
	First-generation Sequencing and Genotyping, and Next-generation		
	Sequencing.		
2001-to-2003	Mammalian Genetics: All first-year genetics student are required to		
	take this class. One lecture taught: Mammalian Genome Analysis.		

b. Graduate student training:

2008-to-2011	Major advisor for Diane Scaduto, graduated with PhD from CMB
	program
2007-to-2010	Thesis committee member for Rocio Benabentos, CMB program
2004-to-2006	Major advisor for Michele Sexton, graduated with MS degree from CMB
	program
2001-to-2007	Major advisor for Wade C. Haaland, graduated with PhD from CMB
	program
2001-to-2005	Thesis committee member for Teresa Venezia, graduated with PhD from
	CMB program
2001-to-2012	Qualifying examination reviewer for 1-2 Genetics & CMR students 2000-to-2012

2001-to-2013 Qualifying examination reviewer for 1-2 Genetics & CMB students 2000-to-2013 First year student rotations (1-2 per year)

c. Post-doctoral training:

	2001-to-2003	Mathew Mahindaratne, Ph.D., now at UT San Antonio	
	2003-to-2004	Ernest Lewis, Ph.D., now at Rice University	
	2003-to-2006	Ming Fa, Ph.D.	
d.	Minority undergraduate student internships:		
-	Summer 2004	Lamin Bangura, now at Ross University Medical School in	
		Dominica(Caribbean)	
	Summer 2005	Rosalie Bangura, now at BCM	
	2006-to-2007	Demetra Farley, now in graduate school at Southwestern Medical	
		Center, Division of Basic Science Program- Cancer Biology training track	
		(began 2007)	
	Summer 2006	Mindy Smith, now at Chicago Medical School of Rosalind Franklin	
		University of Medicine and Science	
	Summer 2006	Quincy Johnson, now at Texas A&M University Graduate School of	
		Engineering (began 2007)	
	Summer 2007	Dionne Watson, student at Prairie View A&M University	
	Summer 2008	Nicholas Chambers, student at Prairie View A&M University	
	Summer 2009	Ogechi Nwaobia, student at University of Texas, Austin	
	Summer 2010	Brian Tenner, Southern Methodist University and Crist Cuffee, Virginia	
		Polytechnic Institute and State University	
	2010-to-2013	Jesse Muniz, University of Texas at Brownsville graduate, B.S. Biology	
e. I	nnovation Norway in H	ouston internships	
	Spring 2011	Liv Arnica Forberg Hovland, now Editorial Assistant/Senior Adviser for	
		the Tax Directorate	
	Spring 2015	Stian A. Weiseth, Norwegian University of Life Sciences, Master of	
		Science student in Innovation and Entrepreneurship	
	Spring 2015	Hanne Hansen, Bergen University College, Master of Science student in	
		Innovation and Entrepreneurship	
	Spring 2016	Espen Svendsen, Bergen University College, Master of Science student in	
		Innovation and Entrepreneurship	
	Spring 2016	Ingrid-Helen Liabø,, Norwegian University of Life Sciences, Master of	
		Science student in Innovation and Entrepreneurship	
	Spring 2017	Axel William Nilsen, Norwegian University of Life Sciences, Master of	
		Science student in Innovation and Entrepreneurship	
f.	Local lectures		
	Jun 2008	Repeat of DNA Day Celebration Lecture for high school students,	
	· · · · · · · · · · · · · · · · · · ·	organized by the Office of Diversity and Community Outreach's Office of	
		Diversity and Community Outreach at BCM	
	Apr 2008	•	
	Apr 2008	DNA Day Celebration Lecture for high school students, organized by the Office of Diversity and Community Outreach at BCM	

IV. Service information:

Administrative assignment:

2002-to-2013 Member: BCM Patent and Copyright Committee 2007-to-2013 Member: HGSC New Faculty Search Committee

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 413 of 739 PageID

EXHIBIT 18C



Nisha Mody, Ph.D.

Managing Director

Nisha Mody, Ph.D., is a Managing Director with Secretariat and specializes in financial and economic consulting on intellectual property cases, business valuation cases, antitrust cases and unfair business practices cases, among others. She is an expert in the application of economic methods to complex business disputes and is retained in cases requiring economic analyses, financial analyses, valuations and/or damages-related analyses. Dr. Mody has constructed damages models in litigation involving reasonable royalties, lost profits, market share assessments, and but-for scenarios. She has also performed valuations of intellectual property (patents and trademarks) as well as valuations of tangible assets, including evaluating damages by applying econometric analyses to large databases.

With more than 20 years of experience in consulting and economic research, Dr. Mody is well regarded among the most prestigious law firms for her expert testimony. Her economic analyses have been affirmed by the Federal Circuit in three matters. She has given deposition/trial testimony in over 80 matters.

In addition to her work with Intensity, Dr. Mody was a Co-Founder/Partner, at Eurekanomics LLC. Prior to that, she served for almost a decade as a Partner for a top tier economic consulting firm. There she worked on many high-stakes litigation projects. Before that, Dr. Mody spent over a decade at leading consulting firms.

Dr. Mody was previously a lecturer at the Santa Clara University School of Law and has authored articles in *Les Nouvelles*.

Dr. Mody received a Ph.D. in Political Economy and Public Policy from the University of Southern California, and a B.A. from Pomona College.

Education

Ph.D. Political Economy and Public Policy, University of Southern California, Los Angeles, 1999. Concentrations: International Economics, Industrial Organization, Antitrust Economics.

B.A. International Relations, Pomona College, Claremont, 1993. Concentrations: Development Economics, Latin American Studies.

Professional Experience

Secretariat (formerly Intensity, LLC). Managing Director, 2021 to present.

Eurekanomics LLC. Co-Founder/Partner, 2020 to 2021.

OSKR, LLC. Partner, 2010 to 2019.

Santa Clara University School of Law, Intellectual Property LL.M. Program. Adjunct Professor/Lecturer, 2010-2012. Course: The Economics and Finance of Intellectual Property.

The CapAnalysis Group, LLC. Managing Principal, 2007 to 2010. Senior Vice-President, 2005 to 2006. Vice-President, 2004. Senior Economist, 2003.

Maxiam, LLC. Senior Advisor, 2003 to 2010.

LECG, LLC (Formerly, LECG, Inc. and Navigant Consulting), Senior Managing Economist, 1999 to 2003.

Econ One Research, Inc. Economist, 1998 to 1999.

Publications and Papers

Mody, Nisha and Evan Schulz: "Anchors Away! An Appeal for Reference Rates When Calculating Prejudgment Interest." (2018) *Les Nouvelles*, 236-241.

Expert Testimony

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CV of Nisha Mody, Ph.D. Page 2 of 8

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CV of Nisha Mody, Ph.D. Page 3 of 8

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CV of Nisha Mody, Ph.D. Page 4 of 8

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CV of Nisha Mody, Ph.D. Page 5 of 8

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CV of Nisha Mody, Ph.D. Page 6 of 8

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CV of Nisha Mody, Ph.D. Page 7 of 8

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CV of Nisha Mody, Ph.D. Page 8 of 8

EXHIBIT 19A

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

AMERICA HOLDING	,	
I	Plaintiff,)	C.A. No. 21-669 (GBW)
V.)	
NATERA, INC.)	
I	Defendant.)	
LABORATORY CORI AMERICA HOLDING)	
I	Plaintiff,	C.A. No. 21-1635 (GBW)
v.))	` '
NATERA, INC.)	
I	Defendant.)	

PLAINTIFF'S MOTION IN LIMINE NO. 1 TO PRECLUDE NATERA FROM CONTESTING VALIDITY UNDER 35 U.S.C. § 101

OF COUNSEL:

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Dated: February 9, 2024

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Attorneys for Plaintiff Laboratory Corporation of America Holdings Pursuant to Federal Rules of Evidence 401, 402, and 403, Invitae seeks to preclude Natera from presenting argument or evidence regarding patent eligibility of the Asserted Patents under § 101. The Court has already spoken on patent eligibility and has ruled that the Asserted Patents are directed to eligible subject matter. D.I. 28 at 4, 7. That ruling is the law of the case.

I. THE ISSUE OF PATENT ELIGIBILITY HAS BEEN DETERMINED

On June 30, 2021, Natera sought to dismiss this case under Rule 12(b)(6), contending that Invitae's '799 patent—which includes claims very similar to those of the other two Asserted Patents—claimed ineligible subject matter under § 101. D.I. 8, 9. After fully considering the motion, Judge Stark found as a matter of law in analyzing *Alice* step one that the '799 Patent is "directed to a specific solution to a technological problem in the field of sequence assembly" and not an abstract idea. D.I. 28 at 4. Judge Stark further found that there was "no need" to evaluate *Alice* step two. *Id.* at 7. This is the law of the case.

Under the law of the case doctrine, when a court reaches a decision regarding an issue of law, "that decision should continue to govern the same issues in subsequent stages in the same case." *Pepper v. U.S.*, 562 U.S. 476, 506 (2011). This doctrine "promotes the finality and efficiency of the judicial process by protecting against the agitation of settled issues." *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800, 816 (1988). The doctrine applies here to the already decided issue of patent eligibility to achieve the same goal here.

The inquiry at "Alice step one presents a legal question that can be answered based on the intrinsic evidence." CardioNet, LLC v. InfoBionic, Inc., 955 F.3d 1358, 1372-73 (Fed. Cir. 2020). Here, the Court found the claims of the '799 Patent are not directed to an abstract idea at Alice step one and that it was "not necessary" to evaluate Alice step two. D.I. 28 at 4, 7. When a court has made such a finding at Alice step one in ruling on a 12(b)(6) motion to dismiss, it is appropriate

for that court to apply the finding as the law of the case. *See Savvy Dog Sys.*, *LLC v. Pennsylvania Coin*, *LLC*, No. 3:19-cv-01470, 2022 WL 4349829, at *5 (M.D. Pa. Sept. 19, 2022) (unnecessary to revisit a court's prior *Alice* step one ruling where there is "no extraordinary circumstance"); *Kove IO, Inc. v. Amazon Web Servs., Inc.* No. 18 C 8175, 2024 WL 450028, at *17-19 (N.D. Ill. Feb. 6, 2024) (invoking law of the case, explaining that "[b]ecause this Court did not proceed to the second step of the Alice inquiry in its previous section 101 analysis, its eligibility decision was a legal determination and thus should not be disturbed absent clear error or another compelling justification.").

The Court's ruling of patent eligibility should be applied with equal force to the '308 and '863 Patents. The '308 and '863 Patents are continuations of the '799 Patent and share the same specification. The claims of the '308 and '863 Patents are also directed to similar patent-eligible subjects as the '799 Patent, teaching, among other things, concrete steps describing "a specific solution to a technological problem in the field of sequence assembly." D.I. 28 at 4; see D.I. 1-1 ('799 Patent) at cl. 1; see also D.I. 57-4 ('308 Patent) at cl. 1; see also D.I. 57-3 ('863 Patent) at cl. 1. Like the '799 Patent, the claims of the '308 and '863 Patents claim steps of (1) obtaining sequence reads; (2) assembling the sequence reads into contigs; (3) placing the contigs along the reference genome; (4) comparing a number of contigs with a reference genome; (5) aligning reads to a number of contigs; and (6) genotyping. See D.I. 1-1 ('799 Patent) at cl. 1; see also D.I. 57-4 ('308 Patent) at cl. 1; see also D.I. 57-3 ('863 Patent) at cl. 1. These limitations are far from abstract. Even Natera's own expert describes the '308 and '863 Patents as "largely repeat[ing] the limitations of the '799 Patent claims" and similar for the purposes of the § 101 patent eligibility test. D.I. 245-1, Ex. D ¶¶ 214, 215.

Thus, the issue of patent eligibility has been decided by the Court for all Asserted Patents.

A. Natera Presents No New Arguments

Natera's purported new arguments are insufficient to overcome the law of the case. *See In re Pharmacy Benefit Mgrs. Antitrust Litig.*, 582 F.3d 432, 439 (3d Cir. 2009) (the law of the case doctrine applies except in "extraordinary circumstances . . . where (1) new evidence is available or (2) a supervening new law has been announced."). For the purely legal issue of patent eligibility under § 101, "dueling expert testimony" in the record does not in and of itself raise a relevant factual dispute. *Mortg. Grader, Inc. v. First Choice Loan Servs. Inc.*, 811 F.3d 1314, 1325 (Fed. Cir. 2016). The Court's claim construction findings are irrelevant as the parties agreed claim construction was not necessary to rule on patent eligibility. D.I. 28 at 7.

To the extent Natera contends that its expert may present new arguments regarding patent eligibility, this is simply wrong. Natera's expert opinions are simply a repackaging of its arguments already presented to this Court. Dr. Metzker describes the claims of the '799 Patent as reciting an algorithm, the argument Natera made in its 12(b)(6) motion to dismiss. *See* D.I. 245-1, Ex. D ¶ 193; *see also* D.I. 9 at 1. As discussed above, Natera itself represents that for the purposes of patent eligibility, the '308 and '863 Patents are subject to the same arguments as the '799 Patent. D.I. 245-1, Ex. D ¶ 215. Thus, Dr. Metzker's report does not constitute new evidence sufficient to create an extraordinary circumstance where the law of the case should be ignored.

For the above reasons, Invitae respectfully requests the Court preclude Natera from contesting the eligibility of the Asserted Patents under 35 U.S.C. § 101.

Dated: February 9, 2024

Respectfully submitted,

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/s/ Brian E. Farnan

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CERTIFICATE OF SERVICE

I, Brian E. Farnan, hereby certify that on February 9, 2024, a copy of PLAINTIFF INVITAE CORPORATION'S MOTION IN LIMINE NO. 1 TO PRECLUDE NATERA FROM CONTESTING VALIDITY UNDER 35 U.S.C. § 101 was served on the following as indicated:

Via E-Mail Via E-Mail Karen Jacobs (#2881) Eric Alan Stone Daniel J. Klein Brian P. Egan (#6227) Eliza P. Strong Derek J. Fahnestock (#4705) Ariella C. Barel MORRIS, NICHOLS, ARSHT & TUNNELL GROOMBRIDGE, WU, BAUGHMAN & LLP 1201 North Market Street STONE LLP 565 Fifth Avenue, Suite 2900 P.O. Box 1347 New York, NY 10017 Wilmington, DE 19899 (332) 269-0030 (302) 658-9200 eric.stone@groombridgewu.com kjacobs@morrisnichols.com dan.klein@groombridgewu.com began@morrisnichols.com eliza.strong@groombridgewu.com dfahnestock@morrisnichols.com ariella.barel@groombridgewu.com natera-invitae@groombridgewu.com Attorneys for Defendant Natera, Inc.

Attorneys for Defendant Natera, Inc.

/s/ Brian E. Farnan Brian E. Farnan

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

C.A. No. 21-cv-669-GBW

C.A. No. 21-cv-1635-GBW

NATERA'S OPPOSITION TO LABCORP'S MOTION IN LIMINE NO. 1

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Exhibit 19

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Labcorp seeks to preclude Natera from "contesting the eligibility of the Asserted Patents under 35 U.S.C. § 101" before this Court, at trial or otherwise. Labcorp's motion overreaches. It asks the Court to make a dispositive ruling on the subject-matter eligibility of three patents when Judge Stark (to whom this case was previously assigned) did no more than deny a Rule 12(b)(6) motion directed at only **one** of those patents and when the full case record, as developed during discovery, shows the ineligibility of **all three** Asserted Patents.

To be clear, Natera does not seek to ask the jury to decide the legal issue of whether the Asserted Claims are patent ineligible under Section 101. But there is no reason why the **Court** cannot decide that issue after trial, in view of the evidence presented. Labcorp does not even attempt to explain why such evidence would be irrelevant, prejudicial, or otherwise prohibited under the Federal Rules of Evidence, and, as Natera shows below, it is not.

I. ARGUMENT

Issues of subject matter eligibility may be decided after trial. See, e.g., Chamberlain Grp., Inc. v. Techtronic Indus. Co., 935 F.3d 1341, 1344–45, 1349 (Fed. Cir. 2019); Intell. Ventures I LLC v. Symantec Corp., 838 F.3d 1307, 1311–12 (Fed. Cir. 2016). That the Court denied Natera's Rule 12(b)(6) motion that the claims of the '799 Patent are patent ineligible is not a basis to preclude Natera from introducing evidence regarding the subject-matter ineligibility of that patent, let alone the other two Asserted Patents. See, e.g., Smartflash LLC v. Apple Inc., 680 F. App'x 977, 978, 980–81 (Fed. Cir. 2017) (reversing denial of JMOL of patent ineligibility, which the district court decided after its summary judgment ruling on the same issue). Indeed, Chief Judge Connolly has rejected such arguments, holding that a prior ruling that patents were not ineligible at Alice step one does not automatically dispose of the issue. See Ex. 1 at 73:2–77:10 (defendant could present Section 101 defense at trial, despite the Court having denied summary judgment at Alice step one); see also Natera, Inc. v. CareDx, Inc., 705 F. Supp. 3d 258, 266 (D. Del. 2023).

Labcorp's cases are either inapt or cut against it. None prohibited the presentation of new evidence of patent ineligibility after a motion-to-dismiss denial based on Alice step one. CardioNet, LLC v. InfoBionic, Inc. says only that Alice step one "can be answered based on the intrinsic evidence," not that it must be, and says nothing about step two. 955 F.3d 1358, 1372–73 (Fed. Cir. 2020) (emphasis added). Kove IO and Savv Dog Sys. both demonstrate why Labcorp's motion should be denied. In Kove IO v. Amazon Web Servs., Inc., the Court granted a summary judgment motion of Section 101 eligibility, finding "there are no changed circumstances or new facts in the record that warrant departing from the law of the case doctrine." No. 18-C-8175, 2024 WL 450028, at *17–19 (N.D. Ill. Feb. 6, 2024). The court in Savvy Dog Sys., LLC v. Pennsylvania Coin, LLC declined to reconsider its motion-to-dismiss holding on the same basis. No. 19-01470, 2022 WL 4349829, at *5 (M.D. Pa. Sept. 19, 2022). But even assuming there was "law of the case" based on a denial of a Rule 12(b)(6) motion (there is not), Labcorp seeks to bar Natera from even presenting evidence that would allow the Court to determine whether there are "changed circumstances or new facts in the record." Kove IO, 2024 WL 450028, at *18. If Labcorp wanted a dispositive ruling under Section 101, it should have moved for summary judgment and afforded Natera the opportunity to present the full evidentiary record supporting its defense. Instead, Labcorp's motion presumes a summary judgment victory it never even sought.

Natera previews here just a few examples of the record evidence it would have marshaled had Labcorp timely sought summary judgment against Natera's Section 101 defense: First, the patents' inventor has now admitted that the patents are directed to an abstract idea. Dr. Porreca testified that he invented "a computational algorithm," see Ex. 2 at 60:11–61:14, the inventive aspect of which "is the combination of multiple steps together," see id. at 70:7–23. See also id. at 102:23–103:1, 105:5–6. Dr. Porreca also contradicted Labcorp's allegation in its Complaint, core

to its Section 101 argument and Judge Stark's ruling, that an advantage of the claimed method is "computational tractability," testifying that any such advantage is achieved from an unclaimed element of his invention. *See id.* at 141:4–143:16; D.I. 13 at 4–5; D.I. 28 at 4–5. Labcorp, too, later jettisoned that motion-to-dismiss argument, persuading the Court during *Markman* that the patented method could be performed with as few as two sequence reads, which would impose no computational burden at all. *See* D.I. 72 at 30 (the claims are satisfied using "some 'sequence reads'); D.I. 84 at 9–11; D.I. 28 at 4–5.

In deciding Natera's motion to dismiss, the Court was required to accept the allegations in Labcorp's (then, Invitae's) complaint. The complete evidentiary record demonstrates that those allegations are incorrect. Natera should be permitted to present that evidence. That includes the testimony of the inventor, Dr. Porreca, and Natera's expert Dr. Metzker, who addressed Section 101 in his reports. *See* Ex. 3 ¶¶ 189–229; Ex. 4 ¶¶ 32–53. Labcorp's expert will have the opportunity to respond with his opinions, disclosed in his report. *See* Ex. 5 ¶¶ 108–131.

Not one of Labcorp's cases addressed a motion *in limine*. And Labcorp is not arguing that Natera's evidence is irrelevant or prejudicial. Labcorp's sole argument is that the Court's denial of a motion to dismiss on one patent is law of the case as to the claims of all three patents, despite evidence later emerging showing their ineligibility. Labcorp cites no law or case precluding the Court from deciding Natera's Section 101 defense after trial, based on evidence presented at trial.

Labcorp's motion has nothing to do with the Federal Rules of Evidence. Instead, in the guise of an *in limine* motion, Labcorp asks the Court to rule on an untimely summary judgment motion that each Asserted Claim is patent-eligible under Section 101. Natera respectfully requests that the Court deny Labcorp's motion, hear both parties' arguments and evidence, and **then** decide, on a post-trial motion, if Natera established the ineligibility of the Asserted Claims.

EXHIBIT 1

1	Case 1:21-cv-01635-GBW Document	302-1 F #: 13186	iled 08/27/25 Page 436 of 739 PageID
2	IN THE UNITED STATES DISTRICT COURT	2	APPEARANCES CONTINUED:
3	FOR THE DISTRICT OF DELAWARE	3	
4	NATERA, INC.,	4	QUINN EMANUEL URQUHART & SULLIVAN, LLP
5	Plaintiff,	5	BY: KEVIN P.B. JOHNSON, ESQ. (via telephone) BY: SANDRA L. HABERNY, ESQ.
6) C.A. No. 20-038 (CFC) v.	6	BY: ANDREW M. HOLMES, ESQ. BY: VALERIE LOZANO, ESQ. (via telephone)
7	CAREDX, INC.,	7	BY: JEFF NARDINELLI, ESQ.(via telephone) BY: ANDREW BRAMHALL, ESQ.
8	Defendant.	8	BY: ABIGAIL CLARK, ESQ. BY: BIANCA FOX, ESQ.
9	,	9	
10		10	Counsel for the Plaintiff
11	Thursday, January 11, 2024	11	
12	3:00 p.m. Pretrial Conference	12	
13		13	
14	844 King Street	14	FARNAN LLP
15	Wilmington, Delaware	15	BY: BRIAN E. FARNAN, ESQ.
16	BEFORE: THE HONORABLE COLM F. CONNOLLY United States District Court Judge	16	-and-
17	United States District Court Dudge	17	WEIL, GOTSHAL & MANGES LLP BY: EDWARD R. REINES, ESQ.
18		18	BY: DEREK C. WALTER, ESQ. Counsel for the Defendant
19	APPEARANCES:	19	counsel for the belendant
20	MORRIS NICHOLS ARSHT & TUNNELL	20	
21	BY: DEREK J. FAHNESTOCK, ESQ.	21	
22	DI: DEREN J. PARNESTOCK, ESQ.	22	
23	-and-	23	
24		24	
25		25	
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1	PROCEEDINGS	1	MR. JOHNSON: Good afternoon, Your Honor.
2		2	THE COURT: Okay. Good afternoon. Thanks.

3 3 All right. Thank you. (Proceedings commenced in the courtroom beginning at 4 3:00 p.m.) 4 MR. FARNAN: Good afternoon, Your Honor. THE COURT: All right. Please be seated. Brian Farnan on behalf of CareDx. And with me is Mr. Fahnestock, welcome. Edward Reines --6 6 MR. FAHNESTOCK: Good afternoon, Your Honor. 7 7 MR. REINES: Good afternoon. MR. FARNAN: -- and Derek Walter from Weil, It's Derek Fahnestock from Morris Nichols on behalf of 8 plaintiff, Natera. Gotshal & Manges. 10 I'll just introduce the team here, all from 10 THE COURT: All right. Thank you. 11 Quinn Emanuel. Sandra Haberny --11 MR. FARNAN: Thank you. 12 MS. HABERNY: Good afternoon, Judge. 12 THE COURT: Had you all thought about how you MR. FAHNESTOCK: Andrew Bramhall -want to proceed, in what order? 13 13 MR. BRAMHALL: Good afternoon. MR. FAHNESTOCK: We haven't actually discussed 14 14 MR. FAHNESTOCK: Drew Holmes -it, Your Honor, but, you know, maybe we could just 1.5 1.5 MR. HOLMES: Good afternoon. discuss a couple of basic procedural trial issues first, 16 16 17 MR. FAHNESTOCK: Abigail Clark, Bianca Fox, 17 like the time of trial and phasing, if that's okay. 1.8 and Tara Srinivasan, I apologize --1.8 MR. REINES: Whatever is best for the Court, MS. SVINIVASAN: Good afternoon. 19 19 frankly. 20 MR. FAHNESTOCK: -- and on the phone. And we 20 THE COURT: All right. Well, I think you 21 thank Your Honor for that accommodation because they were 21 asked for 13, you asked for 11. 2.2 unable to get here based on flights; our lead counsel, 2.2 MR. FAHNESTOCK: That's right. 2.3 Kevin Johnson and Valerie Lozano, as well as Jeff 2.3 THE COURT: I was thinking what about 12 each, Nardinelli 24 and then we don't count closings, and then you each get 25 THE COURT: All right. You want to just --25 an hour or closing. What do you think?

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 437 of 739 PageID #: 13187 amount of time we have or amount of days.

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THE COURT: All right. Next?

MR. FAHNESTOCK: Your Honor, I think

Mr. Bramhall has an issue. We still have an issue where

Your Honor's order, of course, to meet and confer and

narrow the case, we still have issue with the number of

defenses that we think that they want to run.

THE COURT: Okay. You want to do that next?

We have Dauberts. We have to hurry. Let's go.

MR. BRAMHALL: Yeah, understood.

MR. BRAMHALL: Thank you, Your Honor. Andrew Bramhall, again, and I have another visual aid, if that's possible for me to hand up.

THE COURT: Sure. It's possible.

MR. BRAMHALL: May I approach?

THE COURT: Sure.

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better tie it up.

MR. BRAMHALL: Thank you, Your Honor.

So, your Honor, at this stage, on the Natera side we've substantially narrowed our case.

What I've handed you is a document that's showing you at the top our remaining asserted claims. So we're down to five, which is two independent claims, three dependent. We're not hearing any argument from the other side that that's too much or can't be tried in the

Now, on the other hand, if you take a look at what CareDx still has available to them or have not narrowed on their invalidity arguments, and I'm happy to be corrected on any of this from counsel, if there's something on here that shouldn't be. But we have vastly more arguments -- and, in particular, Your Honor, our focus --

THE COURT: I'm not going to limit them.

They've got 12 hours. They will have to get it in. They think they can do this in 12 hours, good for them.

MR. BRAMHALL: If I may, Your Honor, the risk for us is we have all of these defenses we need to now prepare for. Inevitably, to Your Honor's point, some of them are going to fall out, but that's after we've used our time in a prejudicial way.

THE COURT: No, but here's what I'm going to do. I'm going to make them assert these defenses in front of the jury. So if they withdraw them, I'm going to tell the jury. I'm going to tell the jury. They've got to pursue them. They've got to pursue the defenses. They cannot withdraw the defenses.

Now, what I'm going to do is, I will give them to -- what date do you want to pick your final defenses?

MR. REINES: I think we are comfortable with

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these, but if you want to give us until at least tomorrow so we can discuss it.

THE COURT: I just think you have to decide. Because this is the way -- I just did this in another trial, and it worked great is, you are stuck. You must go forward with every defense. The jury will be instructed that you asserted these defenses. And if you withdraw them, I'm going to tell the jury that they asserted these defenses. And I'm going to tell the jury I ruled against them. Because you're not allowed to withdraw them. If you're not going to pursue them, I'm going to tell them.

You cannot blindside people. It's not fair. It's the crappy kind of lawyer behavior I don't like, and it's not right. So pick your defenses.

How long do you want? How much time do you need? You want 24 hours? You want 36 hours? What do you want?

 $\ensuremath{\mathsf{MR}}.$ REINES: Twenty-four hours. We skinnied it down, so we're comfortable.

THE COURT: And I understand that. You might be able to try all of these. Go for it. But what you can't do is you can't walk in and say, we withdrew four of them. Unfair.

 $\mathbf{MR.}$ $\mathbf{REINES:}$ Right. I don't think there's

any --

THE COURT: And, by the way, same thing with them. Because if they really think they're going to try five claims, that's a stretch. And so same thing. You can't withdraw any claims. You are stuck.

So give me the deadline you want, and I will pick it, and you're both stuck.

MR. BRAMHALL: Same timeline works for us, Your Honor; i.e., 24 hours.

THE COURT: 24 hours. You have until 5:00 tomorrow night.

MR. BRAMHALL: Fantastic, Your Honor.

THE COURT: And what you -- final assertion of claims, final assertion of defenses. All right. Next?

MR. BRAMHALL: Thank you, Your Honor.

MR. REINES: Thank you.

I think the next thing, with Your Honor's prompting, is the Daubert.

 $\label{eq:the_court:} \mbox{ Can I just ask you one thing on }$ the 101s?

MR. REINES: Yes.

 $\label{the court:} \mbox{ There was this statement in the letter.}$

 $\label{eq:continuous} \mbox{Do you have the letter?} \mbox{ I have it here. I}$ want you to look at this one, and I'll find my other

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 438 of 739 PageID

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Okay. Mr. Reines, I was going to ask you this. You write in this letter, which is D.I. 423. It's dated January 5th, quote, "With respect to the 101 defense on the '544 patent specifically, CareDx further notes that in view of the rationale of the Court's summary judgment opinion, it understands that this issue is no longer available to be presented to the jury and will seek confirmation on this point at the pretrial conference," unquote.

MR. REINES: Thank you. Yes.

So we're just --

THE COURT: I'm not giving you confirmation because that's not at all the case. I did not make that defense unavailable to you by my ruling.

MR. REINES: Okay. So here's what our rationale was, Your Honor, just so you understand where we're coming from. It wasn't -- our understanding was because you found it a method of preparation, that that was a failure to meet Step 1, and we understood -- I think understand, as Your Honor pointed out the law is not pristine in this area, but that Step 1, I'm never aware of anyone saying that that's a factual-based step, that that's a purely legal step.

Now, you've corrected me on 101 law before,

so -- but on this one, on Step 1 -- so our understanding is since Your Honor -- we're not seeking to lose a defense, right, so it was just -- we want the definitive ruling so were, you know, preserving the record.

So our -- because Your Honor said, "I found it a method of preparation, Step 1 is not satisfied," that we can't go --

THE COURT: Do you have my opinion? I don't remember distinguishing Step 1.

I don't think I made any reference at all to it. I just referred to the fact that the Federal Circuit case law makes clear what the result was.

 $\label{eq:decomposition} \mbox{Does somebody have my opinion?} \quad \mbox{Want to hand} \\ \mbox{it up to me?} \\$

MS. HABERNY: Your Honor, what I recall the opinion saying is that it was found that you denied the Section 101 motion under Illumina. And the Illumina precedent found that a method of preparation was patentable subject matter at Step 1, and said that, from that, you don't need to go to Step 2 to determine issues of fact as to what's routine and conventional.

And so based on that, and I think we had the same understanding, under the Illumina precedent, whether the steps are routine and conventional is no longer at issue because the claim was found to be directed to

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patentable subject matter at Step 1, method of preparation.

THE COURT: Okay. So I think this is a --

 $\label{eq:MS. HABERNY:} \text{And I do have Your Honor's order}$ here, if you would like me to --

THE COURT: Yeah. Can you hand it up to me?

MS. HABERNY: I, unfortunately, have it on a computer.

MR. REINES: E-mail it.

THE COURT: Hold up.

 $\label{eq:MS. HABERNY:} \quad \text{Docket Number 402, Page 13.} \quad \text{And}$ I could read the relevant portion.

THE COURT: Hold on.

Does anybody have a copy of Illumina with

them?

 $\label{eq:mr. reines:} \text{We can bring it up on the screen.}$ I don't know if that helps.

THE COURT: You pointed out to me something I wish I had written better, which is my opinion. And it's funny because I've recently clarified this exact issue in another opinion.

I should never have said that they are patent eligible in that sentence in the first or second paragraph of this opinion, which is located at D.I. 402. They can be patent eligible.

And so, in other words, courts don't engage and they don't find summary judgment to say that a patent is valid and nor do they engage in determining that a patent subject -- or a patent is eligible under 101.

It's a mistake on my part. And what it is, is a patent could be eligible.

So, in other words, it's not, per se ineligible. So I did not mean to preclude or make unavailable the defendants from asserting a 101 defense. They can.

 $\label{eq:solution} \text{So, again, I just wrote this opinion in the} \\ \text{last week or two.}$

 $\label{eq:ms.clark:} \textbf{Ms. clark:} \ \ \textbf{Yeah, you did, Your Honor.} \ \ \textbf{In}$ CR Bard v. AngioDynamics.

THE COURT: Right. And I made the point there, and I didn't find a case that actually says, pointblank, that courts don't declare patents eligible, but they don't. It doesn't make any sense that they would, that you would only do as you do in the invalidity context as a Court, you would only rule that a patent had been proven, by clear and convincing evidence, to be invalid.

Likewise, I would only grant summary judgment that a patent is ineligible, like Bard -- like in the Bard case, I would not say, per se, as a matter of law, a

Document 302-1 Filed 08/27/25 Page 439 of 739 PageID Case 1:21-cv-01635-GBW patent is eligible under 101. Courts don't engage in #: 13189 THE COURT: It's not like it's estoppel, that. right? So to the extent my opinion fairly --MS. HABERNY: I mean, let's just say, suppose -unfortunately, I did not word it as well as I should have 4 in this case, because the issue was not in front of me to 5 THE COURT: Who were the parties in Illumina? think about it that way. But you, the defendants, are 6 Was anybody here a party to that case? allowed to pursue your 101 defense at trial. I did not MR. REINES: Yes, Your Honor. declare as a matter of law that that patent is ineligible 8 THE COURT: Okay. Sorry. Were you -for 101, and then whether it's eligible or not is a MR. REINES: On that one, I was successful, 9 question that remains before me. 1.0 Your Honor. MS. HABERNY: Then, Your Honor, we have a 11 THE COURT: You won? question about how this will be presented to the jury 12 MR. REINES: Yes. because what a patent is directed to, and under Illumina, THE COURT: Yeah. So when you say you, 1.3 being directed to a method of preparation is a question 14 personally, was CareDx a party to that case? of law, not a question of fact. 15 MR. REINES: No. And so that -- I'm presuming now because Your 16 THE COURT: Oh, okay. So my --Honor did find that the patent claims were directed to a $\mathbf{MR.}$ $\mathbf{REINES:}$ Oh, I'm sorry. Me, personally. 17 method of preparation, then I'm not entirely sure what 18 I'm sorrv. could be presented to the jury after that. 19 THE COURT: Yeah. CareDx -- neither CareDx THE COURT: So you're going to argue that 2.0 nor Natera was a party to that case? you're going to look at the factual basis for Step 2 in 2.1 MS. HABERNY: Correct. front of the jury. 22 THE COURT: So there's no estoppel. MS. HABERNY: Well, if, under Illumina, the 23 MR. REINES: So, Your Honor, I think the inquiry did not proceed to Step 2, I'm not sure how this 2.4 issue -- and I have to say I agree with Ms. Haberny to this effect. Your Honor did rule, as a legal matter, as can be presented to the jury. 2.5

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I understood it -- I don't want you to have --

THE COURT: Yeah.

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MR. REINES: But that the way we understand it is that there's not -- it's not claiming -- it's not directed to a natural law or legal principle because it's directed towards a preparation. Okay? Let's just hypothetically say that's what you ruled. If that's what you ruled, then --

THE COURT: What I should have ruled is this, to be very clear. What I said in my opinion at Page 1 into Page 2, I said, quote, "Methods for preparing a fraction of cell-free DNA that is enriched in fetal DNA to make possible the observation of DNA however are patent eligible under Section 101."

What I should have said, "Methods for preparing a fraction of cell-free DNA that is enriched in fetal DNA to make possible the observation of DNA, however, can be patent eligible under 101."

That's what I should have put. All right?

And that's because -- in other words, I don't think -or, and what I would have to think about more is whether
we should have -- well, it may be that a Court could rule
that the Federal Circuit could rule that methods of
preparation are always directed to subject matter that is
patent eligible. That could be -- and I'd have to think

about that.

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And, in fact, I will tell you if you parse the Bard opinion. In Bard, I was actually asked by both sides to engage in exegesis of an unprecedential opinion issued by the Federal Circuit in a Bard case. And in that opinion — again, it's nonprecedential, the Federal Circuit actually did say both that the patents in question were not directed to subject matter eligibility. And then about a sentence or two later, the Federal Circuit said "The patents are eligible under 101."

And one of the parties asked me to focus on those two sentences to say that the Federal Circuit has declared as a matter of law that the patents asserted in that case, which were asserted in the case before me, are valid or are eligible under 101 as a matter of law. And I said I can't do that. But I agreed that those two sentence supported the argument that that's what the Federal Circuit had done.

I also said that if you look up at a couple of sentences before those two sentences, you will see where the Federal Circuit defined what was the question before it, which supported the other party's position. All right?

But the bottom line, what I did is I only made reference in my opinion to the sentence that talked about $\ensuremath{\mathsf{I}}$

115

I hereby certify that the foregoing is a true and accurate transcript from my stenographic notes in the proceeding.

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/s/ Bonnie R. Archer Bonnie R. Archer Official Court Reporter U.S. District Court

EXHIBIT 2

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Page 1
 1
                                                 I
                                     VOLUME:
                                     PAGES:
                                                 1-326
 2
                                     EXHIBITS: 1-33
 3
                  UNITED STATES DISTRICT COURT
 4
                    FOR THE DISTRICT OF DELAWARE
 5
                       NO. 1:21-cv-01635-LPS
 6
 7
 8
     INVITAE CORPORATION,
                                           )
 9
                       Plaintiff,
                                           )
10
                    vs.
                                           )
11
     NATERA, INC.,
12
                       Defendant.
13
14
15
                        VIDEOTAPED DEPOSITION OF INVITAE
16
     CORPORATION BY GREGORY J. PORRECA, PhD, called as a
17
     witness by and on behalf of the Defendant, pursuant
18
     to the applicable provisions of the Federal Rules
19
     of Civil Procedure, Rule 30(b)(6), before P. Jodi
20
     Ohnemus (remotely), RPR, RMR, CRR, CA-CSR #13192,
21
     NH-LSR #91, MA-CSR #123193, and Notary Public,
     within and for the Commonwealth of Massachusetts,
22
23
     at Cambridge, Massachusetts, on Friday, April 28,
24
     2023, commencing at 9:47 a.m.
25
```

CONFIDENTIAL				
Page 58				
1 A. Yes. This would be the first diagram of	1 A. Tom Meyers was our IP attorney at the time			
2 the algorithm.	2 for the company.			
3 Q. Let's look at Exhibit 5 to your	3 Q. In house or outside counsel?			
4 deposition, and then I'm going to want a break in a	4 A. Outside counsel.			
5 minute 'cause I can hear my voice going. But let's	5 Q. And it says (as read):			
6 look at Exhibit 5 for a moment.	6 "On what date did you make such a			
7 (Exhibit 5, Invention Disclosure Form,	7 disclosure?"			
8 ML-PORRECA000000068-74.)	8 Answer: "September 28, 2011."			
9 A. Okay.	9 You see that?			
10 Q. Doctor Porreca, I've placed before you	10 A. I do see that.			
11 what I've marked as Exhibit 5 to your deposition,	11 Q. Fair to say, then, that you had the idea			
12 which bears the Bates numbers ML-PORRECA 68 through	12 on September 27, 2011, and were in a position to			
13 74. It's a document entitled "Invention Disclosure	13 disclose the idea to your lawyer the next day?			
14 Form."	14 A. That's what this document indicates.			
Do you see that there?	15 Q. Is it right?			
16 A. I do.	16 A. As far as I can remember, I believe it is			
17 Q. It lists as the people who conceived of	17 correct.			
18 and/or reduced to practice the invention, yourself	18 Q. On the top of the next page it says (as			
19 and Doctor Kennedy; correct?	19 read):			
20 A. That is correct.	20 "When did you first do any experimental			
21 Q. And then there is a section entitled	21 work towards carrying out the invention?"			
22 "Description of the Invention"?	You see that there?			
23 A. Yes.	23 A. I do.			
24 Q. And that continues on for a couple of	Q. And the answer is "N/A."			
25 pages; and on page 4 of this document actually has	25 A. Yes.			
Page 59	Page 61			
1 the photograph of the whiteboard; correct?	1 Q. Is that meaning not applicable?			
2 A. That is correct.	2 A. Correct.			
3 Q. Then it says (as read):	3 Q. And the reason that that's your answer is			
4 "When did you first think of this	4 that you didn't do any experimental work towards			
5 invention?"	5 carrying out the invention; correct?			
6 Answer: "September 27, 2011."	6 A. That's correct, because it was a			
7 Is that right?	7 computational algorithm.			
8 A. That's correct.	8 Q. Right. The the invention is a			
9 Q. And I guess I should ask two questions:	9 computational algorithm. It's not something that			
10 That's what it says. And it's accurate; correct?	10 you do physically; correct?			
11 A. That is what it says. And that is	11 A. It's not something that I I think			
12 accurate.	12 the way I answered that question was it's not some			
Q. Thank you. And it says (as read):	13 kind of a wet lab technique. It's a computational			
"What record do you have to substantiate	14 algorithm.			
15 this date?"	Q. And then you say, (as read):			
Then it says (as read):	16 "When did you first make written			
17 "This disclosure, email from Greg to Cale				
18 with photo of whiteboard outlining method."	18 Answer: "September 27, 2011."			
19 You see that?	19 You see that there?			
20 A. I do see that.	20 A. I do.			
Q. And it says (as read):	21 Q. Now, on every page of this document you			
22 "To whom did you first disclose this	22 and Doctor Kennedy have signed it and dated it			
23 invention?"	23 November 7, 2011, other than the last page; is that			
And the answer is "Tom Meyers."	1.71.4			
Who's that?	24 correct? 25 A. So there's a signature there are two			

16 (Pages 58 - 61)

CONFIDENTIAL

1 signatures and dates on every page at the bottom.

- 2 I think that's what you're referring to. That --
- 3 those signatures are mine and someone named Mark
- 4 Umbarger. That's not Caleb Kennedy's signature.
- 5 Mark --
- Q. So -- go ahead. Please continue.
- 7 A. Mark was the person who witnessed this.
- Q. Okay. So I was obviously wrong about
- 9 that. With no disrespect to Mr. Umbarger, those
- 10 lines could be essentially any name. So I'm going
- 11 to start over and just get it correct. I have no
- 12 interest in having you tell me something that isn't
- 13 true. So thank you. Withdrawn.
- 14 If we direct you to the bottom of the
- 15 first page, we see your signature dated November
- 16 7th, 2011, and the signature of somebody named Mark
- 17 Umbarger, who is acting as the witness; correct?
- 18 A. That's correct.
- 19 Q. Who is Mr. or Doctor Umbarger?
- 20 A. Doctor Umbarger was another person who
- 21 worked for me in the R&D department at Good Start.
- 22 He was a Good Start employee.
- Q. I want to try to understand the sequence
- 24 in which things happened.
- 25 If you turn to the last page of this

Page 62 1 what happened or why it looks that way.

- Q. All right. That's fair. And whatever --
- 3 but do you understand that to be Mr. Umbarger's
- 4 signature?
- 5 A. I do, yes.
- Q. All right. And to the right of it it says
- 7 November 7th, 2011?
- A. Yes, it does.
- Q. And then you and Mr. or Doctor -- forgive
- 10 me -- Umbarger signed all the other pages of this
- 11 document on November 7th, 2011?
- 12 A. Yeah. That's the -- that's the date.
- 13 Q. Do you have an understanding of how that
- 14 happened? So it looks like you signed it on the
- 15 28th and he witnessed it. And then, you know, a
- 16 month and a half later -- or whatever that is --
- 17 Doctor Kennedy signed it and you signed every page.
- 18 How'd that all happen?
- 19 A. I don't recall.
- 20 Q. Okay. That's fair.
- 21 MR. STONE: I'm going to ask that we take
- 22 a ten-minute break here because I obviously need
- 23 some water. We've been going a little while. Is
- 24 that okay with everyone else?
- 25 THE WITNESS: Yes.

Page 63

3

Page 65

Page 64

- 1 document.
- 2 A. Yes.
- 3 Q. Am I right that the first inventor
- 4 signature is Gregory Porreca. That's you?
- 5 A. That's correct.
- Q. And it's dated September 28, 2011. 6
- 7 You see that?
- 8 A. I do.
- Q. And, then, five lines down under "Witness
- 10 signature," there's what I think is Mark Umbarger's
- 11 signature; correct?
- 12 A. That is correct.
- Q. Also dated September 28, 2011; correct? 13
- 14 A. That is correct.
- 15 Q. Is the second signature on the page Caleb
- 16 Kennedy?
- 17 A. I believe it is, yes.
- 18 Q. And it's dated 7 November 2011; correct?
- 19 A. Yes. Correct.
- 20 Q. And, then, I think what's happening in the
- 21 second "Witness Signature" is that Mr. Umbarger
- 22 wrote his name, for whatever reason didn't like the 23 way it looked, crossed it out, and wrote it again.
- 24 Is that what you see there?
- 25 A. I see a bunch of scribbling. I don't know

- 1 VIDEO OPERATOR: We're now going off the
- 2 record at approximately 10:58 a.m. (Recess was taken.)
- 4 VIDEO OPERATOR: This is the beginning of
- 5 media No. 2. We're going back on the record at
- 6 approximately 11:16 a.m.
- 7 Go ahead, sir.
- Q. Dr. Porreca, when we broke we were looking
- 9 at the invention disclosure form for the invention
- 10 that became the '799 patent; correct?
- 11 A. That is correct.
- 12 Q. All right. Let's -- let's look at it
- 13 again together. I want to start with just, sort
- 14 of, geography. Directing you to the "Description
- 15 of the Invention" section, the first paragraph
- 16 there that says "Please provide a concise
- 17 description," that paragraph is part of the form
- 18 that you fill in; correct?
- 19 A. That is correct.
- 20 Q. All right. And then the stuff that you
- 21 filled in begins with the words "Analysis of
- 22 sequence data"; correct?
- 23 A. That's correct.
- 24 Q. And if you look at that part of the first
- 25 page and then into the second page, you'll see on

9	e 1:21-cv-01635-GBW Document 302-1 #: 1319 CONFID	
	Page 66	Pa
	1 the second page there's a paragraph that says (as	1 Do you see that there?
	2 read):	2 A. I do see that.
	3 "The invention described here."	3 Q. And then it says (as read):
	4 You see that?	4 "The process is as follows."
	5 A. Yes.	5 And there are six numbered paragraphs
	6 Q. Am I correct that the text in that section	6 below that; correct?
	7 above the words "the invention described here" that	7 A. Yes, there are.
	8 is the paragraph that begins "Analysis of sequence	8 Q. And is it fair to describe those six
	9 data" and the two numbered paragraphs under it and	9 numbered paragraphs as each being a step of the
	10 the paragraph that begins "The advantage of this	10 process?
	11 approach" and the three numbers numbered	11 MR. PEPE: Object to form.
	12 paragraphs after it, all of that is your	12 A. (Witness reviews document.) Yeah. The
	13 description of the prior art of what was known	13 are the high-level look like steps of the
	14 before; correct?	14 process to me.
	15 A. (Witness reviews document.) I'm reviewing	15 Q. Step 1 is (as read):
	16 it now.	16 "Assemble a set of reads into one or more
	17 Q. Of course. You should.	17 contigs."
	18 A. (Witness reviews document.) So I think	You see that there?
	19 that text is a description of certain aspects of	19 A. I do see that.
	20 the prior art that we thought were relevant and	20 Q. Your invention is not strike that.
	21 that, in part, motivated the invention.	There are a number of different algorithms
	22 Q. And, then, the part that is a description	22 that one can use to assemble reads into contigs;
		1

25 here." A. (Witness reviews document.) This -- this 1 2 is a description of the algorithm. When we say a description of the 4 invention, that sounds a little precise to me. I 5 think this is -- this was -- our intent here was to 6 describe the algorithm that we had come up with. 7 Q. Okay. I -- I'm -- I'm not looking to use 8 the words in a limiting way. I'm looking to 9 understand the structure of the document. So maybe 10 we can do it this way -- withdrawn. The words before "The invention described 12 here" are your attempts to describe aspects of the 13 prior art and some of the problems with those 14 aspects of the prior art. And the words that begin 15 with "The invention described here" and flow onto 16 the next page are a description of the algorithm 17 that you have come up with and how it helped solve 18 those problems; is that fair? 19 A. Yes, that's fair. 20 Q. And you write (as read): 21 "The invention described here is a method 22 to reliably detect indels of increased length as 23 well as substitutions located in cis with indels or

24 with multiple other substitutions that prevent

23 of the invention, unsurprisingly, is the part that

24 begins with the words "The invention described

ee that there? that. n it says (as read): cess is as follows." e are six numbered paragraphs rect? re are. fair to describe those six graphs as each being a step of the E: Object to form. s reviews document.) Yeah. These vel -- look like -- steps of the (as read): le a set of reads into one or more hat there? that.

Page 68

Page 69

25 A. Yeah, I don't think this specifies what

MR. PEPE: Object to form.

1 algorithm you would use to do that assembly 2 process. 3 Q. I don't either, but you're two questions

4 ahead of me. We're going to get there in a moment.

5 Just stay -- stay with me. I -- I don't think any 6 of this is going to be a surprise. I don't even

7 think we disagree about it, but let's just go one

8 question at a time if we could. Okay?

9 A. Okay.

23 correct?

24

10 Q. At the time of your invention on September

11 27 of 2011 there were multiple algorithms already

12 known in the art for how to combine reads into

13 contigs; correct?

14 A. Yes, that's correct.

15 Q. Right. And you don't purport to have

16 invented a new algorithm for combining reads into

17 contigs. Your invention can be practiced with any

18 of those algorithms; correct?

19 MR. PEPE: Object to form.

20 A. The invention can use different assembly

21 algorithms. It was conceived at the time to use

22 assembly as a generic process.

23 Q. And just to be -- withdrawn.

24 You didn't invent a new assembly algorithm 25 for assembling reads to contigs as part of this

18 (Pages 66 - 69)

25 alignment."

CONFIDENTIAL					
	Page 70		Page 72		
1 invention; correct?		1	The step of the GATA algorithm that is the		
2 A. We did not inve	ent a new assembly algorithm	2	'799 patent, one step of that requires assembling		
3 to assemble reads. The	e assembly algorithm sits	3	reads into contigs; correct?		
4 inside of the larger GA	ATA algorithm.	4	A. Yes.		
5 Q. And let's talk at	bout that for a second.	5	Q. And there may be many ways in which one		
6 GATA is a set of str	rike that.	6	can do that as one step of the GATA process;		
7 The GATA algor	rithm has a number of steps		correct?		
8 within it; correct?	1	8	A. That's correct.		
9 A. That is correct.		9	Q. And the GATA algorithm doesn't require any		
10 Q. And your conte	ntion is that the overall	10	particular means of assembling reads into contigs.		
11 algorithm is inventive;			It just requires that reads be assembled into		
12 A. That is correct.			contigs; correct?		
13 Q. But some of the		13	A. I don't know that I don't know that I		
14 as part of that algorithm		14	would say it doesn't require any particular means.		
15 were already doing, like			I think it it does require reads to be assembled		
16 contigs; correct?	-		into contigs. I'm sure there are assembly methods		
17 A. That is correct.			that well, I would imagine there are assembly		
18 Q. And you're not			methods that wouldn't work with this process.		
19 that every step of the a	-	19	Q. What the GATA strike that.		
20 inventive. What's inve	entive is the overall	20	What the GATA algorithm of the '799 patent		
21 algorithm; correct?		21	requires in this step is that the reads be		
22 A. That is correct.	The inventive part of	22	assembled into the contigs, but it doesn't dictate		
	-	23	a particular means of doing that; correct?		
		24	A. That is correct.		
25 the steps some whet	her some of them were already 2	25	Q. And, then, in step 2 of the GATA algorithm		
	Page 71		Page 73		
1 known in the art, and v	-	1	as set forth in this invention disclosure, you (as		
2 suggesting that means	the overall algorithm was	2	read):		
3 known in the art. I'm j	just going to ask you about	3	"Determine the genomic position of each		
4 each individual step be	ecause I want to figure out		contig generated in step 1 and identify any		
5 what the pieces are. A	and that that's the reason	5	differences between that contig and the reference		
6 I'm asking. So withdra			genome (substitutions and indels)."		
7 As of September	27, 2011, the idea of	7	Do you see that there?		
8 assembling reads into	contigs, assembling reads	8	A. I do see that.		
9 into contigs was know	n in the art; correct?	9	Q. And it says that (as read):		
10 A. Yes, it was.		10	"This can be done using BWA-long."		
	1	11	You see that?		
-	υ , ,	12	A. I do.		
13 A. That is correct.		13	Q. BWA-long is a software algorithm that		
1	-		existed before September 27, 2011; correct?		
15 any method of assemb	0	15	A. That is correct.		
16 simply requires that re		16	Q. And the idea of aligning contigs strike		
17 contigs; correct?			that.		
I .	1	18	The idea of aligning contigs to a		
19 any method. It can be			reference genome and identifying differences		
Q. That's a very			between the contig and the reference genome was		
21 A performed wi			known in the prior art before September 27, 2011;		
22 multiple methods.			correct?		
-	· · · · · · · · · · · · · · · · · · ·	23	A. I don't know that it's true that the idea		
24 I'm going to ask it that	,		of taking reads, assembling assembling them into		
25 Your GATA algo	orithm withdrawn.	25	a contig, and then aligning them to a reference		

Page 98

- 1 A. Yes.
- 2 Q. First off, am I correct that each of these
- 3 is a file format for computer data which is why
- 4 they begin with a period?
- 5 A. That is correct. This looks like -- yes,
- 6 this looks like a -- an attempt to indicate what
- 7 our internal file formats were for each step.
- 8 Q. The first one, ".fq," is something that
- 9 was known in the art as FASTQ, F-A-S-T-Q; correct?
- 10 A. That is correct.
- 11 Q. And that's not a file format that you
- 12 invented as part of the GATA algorithm in the '799
- 13 patent. That was in the prior art; correct?
- 14 A. Correct.
- 15 Q. The second one is ".fa," that's FASTA,
- 16 F-A-S-T-A; correct?
- 17 A. Yes. I believe that's correct.
- 18 Q. And that also is an algorithm -- strike
- 19 that.
- That also is a file format that was known
- 21 in the prior art. You didn't invent that as part
- 22 of this; correct?
- 23 A. Correct.
- Q. Do you know what "Remove base qualities"
- 25 is in step 1?

- Page 99
- A. It may be that the assembly tool that we
- 2 were using needed an input format that didn't
- 3 contain the base qualities, but I -- I don't know
- 4 for sure.
- 5 Q. Okay. The -- whatever it is, it is the
- 6 difference between the prior art FASTQ format and
- 7 the prior art FASTA format; correct?
- 8 A. I think that this is indicating that the
- 9 steps line up with the boxes, with the arrows --
- 10 Q. Uh-huh.
- 11 A. -- between the boxes. I think that's what
- 12 this is indicating.
- 13 Q. Right. And so whatever "remove base
- 14 qualities" is, it's a description of how you
- 15 convert a FASTQ into a FASTA; correct?
- 16 A. That seems like a reasonable explanation.
- 17 As far as I know, a FASTA does not include base
- 18 qualities.
- 19 Q. And what are base qualities?
- 20 A. Those are characters in the file that
- 21 describe the accuracy of the base calls or the
- 22 letters, the A, Cs, Gs, and Ts in that file.
- 23 Q. And just to be clear, that's not alignment
- 24 information. The reads are unaligned. The base
- 25 quality is how good a read is this; correct?

Page 100

- 1 A. The base quality is how good each -- each
- 2 letter in the read is.
- 3 Q. Right. And -- and just to close off that
- 4 loop, there's no alignment information in any of
- 5 that; correct?
- 6 A. That is correct. There's no -- those base
- 7 qualities do not encode alignment information. The
- 8 FASTQ file has not been -- is not the output of an
- 9 alignment algorithm.
- 10 Q. And so we see FASTQ information, the
- 11 unaligned reads being assembled into read -- strike
- 12 that.
- 13 I -- I want to ask a question -- I'm going
- 14 to come back to that in a second.
- Where it says "Assemble reads," No. 2?
- 16 A. Yeah
- 17 Q. It's referring to assembling reads into
- 18 contigs, not assembling letters into reads;
- 19 correct?
- 20 A. That is correct.
- 21 Q. All right. So now I can go back to where
- 22 I was, but I want to just make sure I understood
- 23 that. Thank you for bearing with me. Withdrawn.
- And so on the left part of this flow chart
- 25 we see unaligned reads being assembled into a

Page 101

- 1 contig in step 2; correct?
 - 2 A. Yes.
- 3 Q. We then see that contig made from the
- 4 unaligned raw reads being aligned to the reference
- 5 genome in step 3; correct?
- A. That's correct.
- 7 Q. We then see the generation of an indexed
- 8 reference, which is how does the contig compare to
- 9 the reference genome in terms of where on the
- 10 genome is it and how are they different from each
- 11 other, if at all; correct?
- 12 A. No. I think that that step is referring
- 13 to something that has to happen before you can use
- 14 BWA-short on the read data. BWA-short is an
- 15 algorithm that takes a reference genome as an input
- 16 1 4 6 1 4 1 4
- 16 and a set of reads as another input.
- 17 Q. Right.
- 18 A. But reference genome has to be converted
- 19 into something called an index first.
- 20 O. Got it.
- 21 A. So I think what this diagram is showing is
- 22 that those contigs had to be turned into an index
- 23 before they could be used as a reference genome for
- 24 BWA-short.
- 25 Q. Okay. And then at the top of -- well,

26 (Pages 98 - 101)

CONFIDENTIAL				
Page 102	Page 104			
1 strike that.	1 Q. Well, to be to be fair, the			
2 I want to make sure I understand the way	2 algorithm the patent goes on to then claim using			
3 the diagram works.	3 genotyping.			
4 What the flow chart is showing us is that	4 So I I don't mean it in you know			
5 the FASTQ data becomes a FASTA file, then a contig,	5 what? Let I that's that's a fair answer,			
6 then a sam file, then a FASTA file again, and then	6 and we're going to come to that.			
7 it goes back up to the top and it gets rejoined	7 Withdrawn.			
8 with the FASTQ data to become a BAM file; correct?	8 Step 6 of this diagram within the			
9 A. I think the diagram is a little confusing,	9 invention disclosure for the '799 patent is to			
10 actually, because that step 4, "Generate an indexed	10 genotype; correct?			
11 reference," I don't think the output of that	11 A. That's correct.			
12 indexing process would be a FASTA file.	12 Q. The input to that genotyping process is			
13 Q. I was going to ask that next.	13 shown as being a BAM file; correct?			
14 Generally what this is trying to show us	14 A. That's correct.			
15 is that the raw reads get converted into a	15 Q. And the output is shown as being a .vcf			
16 contig strike that.	16 file; correct?			
17 Generally what this diagram is claiming is	17 A. That's correct.			
18 the invention or part I'm having a hard one	18 Q. And a .vcf file is one of the file formats			
19 here. Give me a moment. Withdrawn.	19 that was known in the prior art as the output from			
We're looking at the invention disclosure	20 a genotype caller a variant caller; correct?			
21 for what became the '799 patent; correct?	21 A. That's correct.			
22 A. Yes.	Q. And, again, you don't purport to have			
Q. And we're looking at a flow chart that	23 invented the VCF file format or the BAM file format			
24 attempts to summarize the algorithm of the '799	24 or any particular variant calling software as part			
25 patent; correct?	25 of the '799 patent; correct?			
Page 103	Page 105			
1 A. Yes.	1 MR. PEPE: Object to form.			
2 Q. And what it is showing us is raw unaligned	2 Q. Go ahead.			
3 reads are combined to form a contig. That contig	3 A. We don't purport to have invented the VCF			
4 is aligned to the reference genome to see how the	4 file format.			
5 contig differs, if at all, from the genome and	5 I would consider the overall algorithm to			
6 where it aligns; and then that information is	6 be a variant calling algorithm. 7 O. Let's look at the patent together. It's			
7 combined with the raw reads again to interpret how 8 do the raw reads align to the reference genome and	1 8			
	8 Exhibit 2.			
9 how are they different than the reference genome,10 if at all; correct?	9 A. Okay. 10 Q. I want you to look at first column 5?			
11 A. I think at a high level that summary is	11 A. Okay.			
12 correct, yes.	12 Q. You'll see in the middle of column 5 sort			
13 Q. And all of the steps that precede the	13 of lower middle, a section called "Brief			
14 genotyping step are steps that result in a BAM	14 Description of the Drawings."			
15 file; correct?	15 A. Yes.			
16 A. Those steps result in a number of files,	16 Q. No. 1 says (as read):			
17 but a BAM file is one of them. And the BAM file	17 "Figure 1 is a diagram of methods of the			
18 would would reflect the output of that final	18 invention."			
19 alignment step.	19 Do you see that?			
20 Q. So one way of encoding the output of the	20 A. I do.			
21 '799 patent algorithm is as a BAM file; correct?	21 Q. Let's go look at figure 1 together. Flip			
22 A. I would need to review the '799 patent. I	22 back a few pages.			
23 don't know if that's I can't remember if that's	23 A. Okay.			
24 where the algorithm ends that's claimed in that	Q. Do you see here a a different flow			
25 patent.	25 chart?			
	I .			

e 1:21-cv	-01635-GBW Document 302-1 #: 1319 CONFID	9	ed 08/27/25 Page 449 of 739 PageID
	Page 106		Page 108
1 A.	I do.	1	A and in that case you're not obtaining a
2 Q.	You'll notice on the left that each of the	2	nucleic acid sample.
3 six ite	ms in the flow chart has a number assigned	3	Q. Okay. Let's look at column 5, line 60.
4 to it.		4	It says (as read):
5	You see those?	5	"Nucleic acid in a sample can be any
6 A.	I do.	6	nucleic acid, including, for example, genomic DNA
7 Q.	And I will represent and we'll look	7	in a tissue sample, cDNA amplified from a
8 togeth	er that the patent from time to time	8	particular target in a laboratory sample, or mixed
9 refers	to each of these steps by these numbers.	9	DNA from multiple organisms."
10 I	Do you know where the numbers came from?	10	Do you see that there?
11 Like w	why it's 101, 105 as opposed to 102?	11	A. I do.
12 A.	(Witness reviews document.)	12	Q. And I want you to look now at column 9.
13 I	think I could review the patent and tell	13	A. Okay.
14 you.		14	Q. And specifically at line 52 where it says
15 Q.	Okay. If you see something along the way	15	(as read):
16 that	we're going to go through a fair bit of the	16	"After any processing steps (for example,
17 patent	. So if you see something along the way, let	17	obtaining, isolating fragmenting, or
18 me kn	ow. But why don't we start by looking at	18	amplification), nucleic acid can be sequenced
19 colum	n 12 together.	19	according to certain embodiments of the invention."
20 A.	Okay.	20	You see that there?
21 Q.	It says at around line 34 (as read):	21	A. I do.

"Figure 1 is a diagram of methods of the

22 23 invention. Methods include obtaining 101 sequence

24 reads and assembling 105 then into a contig, which

25 is then aligned 109 to a reference. Differences

1 are identified by comparison 113. The raw reads 2 are aligned 117 to the contigs and positional and

Page 109

Q. I want you to just run your eyes along

23 columns -- this section of the patent from column

24 5, line 60 to column 9, line 54 -- or 55, wherever

25 that ends, and look at the description of how one

3 variant information is mapped to the reads from the

4 reference via the contig allowing genotyping 121 to

5 be performed."

You see that there?

7 A. I do.

Q. That paragraph is using the numbers in

9 figure 1; correct?

10 A. Yes.

Q. Does it do anything to trigger a 11

12 recollection as to why those were the numbers?

13 A. No, it doesn't.

14 Q. Okay. I want to walk through where the

15 patent talks about each of the steps of the method.

16 So let's start in column 5, the detailed

17 description.

18 A. Okay.

19 Q. Okay. Will you agree with me that in

20 order to obtain reads you have to first start with

21 a nucleic acid sample?

22 A. I -- maybe. I think -- I mean, you

23 could -- you could go to the internet and download

24 reads ---

25 Q. True. 1 goes about obtaining nucleic acid samples for

2 purposes of carrying out the invention as

3 described.

22

Page 107

4 Take a minute to just look at those

5 sections.

A. (Witness reviews document.) Okay.

7 Q. All right. Have you had an opportunity to

8 look at the parts of the '799 patent that are

9 between column 5, line 60 where it begins talking

10 about nucleic acid, and column 9, line 55 where it

11 stops talking about nucleic acids?

12 A. Yes, I have.

Q. And is it fair to say that everything in

14 that section of the patent, from column 5, line 60

15 to column 9, line 55, was known in the prior art?

16 MR. PEPE: Object to form.

17 A. I haven't had a chance to review that.

18 I -- I don't think I can say that after scanning

all of that text.

Q. Is there anything that you think you

21 invented about nucleic acid preparation as part of

22 the invention of the '799 patent?

23 MR. PEPE: Same objection.

24 A. I don't -- I don't think so. I'm not sure

25 I understand your question.

CONFIDENTIAL					
Page 138	Page 140				
1 the court reporter's.	1 if you feed it ten times as much information, it				
2 VIDEO OPERATOR: Let's go off the record.	2 would take 100 times as long.				
3 We're now going off the record at 12:50 p.m.	3 Q. So let's look at the '799 patent again,				
4 (Whereupon the deposition recessed at	4 Exhibit 2 to your deposition, and let's look at				
5 12:50 p.m.)	5 column 2 together.				
6	6 A. Sorry. Which exhibit was that again?				
7	7 Q. I believe the patent is Exhibit 2.				
8	8 A. Okay.				
9	9 Q. It is, yes.				
10	10 A. And what column?				
11	11 Q. Column 2. And remember the columns start				
12	12 after the drawings.				
13	13 A. Right. Okay.				
14	14 Q. Okay. There's a section in column 2				
15	15 entitled "Summary."				
16	16 You see that there?				
17	17 A. Yes.				
18	18 Q. And you know from your experience as an				
19	19 inventor on patents that that section is generally				
20	20 at a high level a summary of the invention claimed				
21	21 in the patent; correct?				
22	22 A. Yes.				
23	23 Q. I'd like to direct you to lines 39ish in				
24	24 that paragraph, the words at the right side say,				
25	25 "By assembling."				
Page 130	Page 141				
Page 139 1 AFTERNOON SESSION (1:39 p.m.)	Page 141 Do you see that?				
1 AFTERNOON SESSION (1:39 p.m.)	1 Do you see that?				
1 AFTERNOON SESSION (1:39 p.m.) 2 VIDEO OPERATOR: This is the beginning of	1 Do you see that? 2 A. I do.				
1 AFTERNOON SESSION (1:39 p.m.) 2 VIDEO OPERATOR: This is the beginning of 3 media 3. We're now going back on the record at	1 Do you see that? 2 A. I do. 3 Q. It says (as read):				
1 AFTERNOON SESSION (1:39 p.m.) 2 VIDEO OPERATOR: This is the beginning of 3 media 3. We're now going back on the record at 4 approximately 1:40 p.m.	1 Do you see that? 2 A. I do. 3 Q. It says (as read): 4 "By assembling reads into contigs or				
1 AFTERNOON SESSION (1:39 p.m.) 2 VIDEO OPERATOR: This is the beginning of 3 media 3. We're now going back on the record at 4 approximately 1:40 p.m. 5 Go ahead, sir.	 Do you see that? A. I do. Q. It says (as read): "By assembling reads into contigs or contigs as well as aligning the individual reads to 				
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	Page 142		Page 144			
	1 Q. Why would you compare each of the reads to	1	The the '799 algorithm does not require			
	2 all of the other reads in the prior art methods?	2	that the reads be aligned to the reference genome			
	3 MR. PEPE: Object to form.		before they are turned into contigs; correct?			
	4 Q. You can answer.	4	MR. PEPE: Object to form.			
	5 A. I think that this is getting at the idea	5	A. It doesn't require that, and that's not			
	6 that when the assembly is done here the assembly is	6	that's not how reads were being grouped prior			
	7 not performed on all of the reads from the		assembly. There was no alignment process			
	8 experiment. It's only performed on the the		occurring.			
	9 group of reads that came from a specific region in	9	Q. Okay. That was my understanding as well.			
	0 the target genome. And as a result of that, you're		So I want to just be clear on that.			
	1 able to limit the amount of computation that's	11	So withdrawn.			
	2 required to perform the assembly.	12	What happens here is (as read):			
1		13	"A method for assembling sequence reads,			
- 1	4 assembly algorithms, including the one that that	14	the method comprising" I want to read together.			
	5 we were contemplating here, the the runtime	1	Are you with me?			
	6 grows exponentially with, I think, kind of the	16	A. Uh-huh.			
	7 number of reads or the length, the total length of	17	Q. (As read):			
	8 what's being assembled; and so by keeping that	18	"obtaining a sample comprising template			
	9 narrower and performing the assembly in chunks,		nucleic acid; sequencing the template nucleic acid			
	0 you're able to get around that problem.		to generate a plurality of sequence reads."			
2		21	Plurality, as you know, is a group of more			
2	2 patent, assuming that you have a PDF version, you	22	than one.			
	3 should be able to go to the last page and then back	23	A. Yes.			
	4 up one. I'd like you to look at the second-to-last	24	Q. (As read):			
	5 page of the exhibit.	25	"inputting a reference genome and said			
	Page 143		Page 145			
	1 A. Yeah.	1	plurality of sequence reads into a computer			
	Q. All right. You're in column 26?		system."			
	3 A. I am.	3	You see that?			
	Q. What is claimed you see at the bottom	4	A. Yes.			
	5 "What is claimed is" and then there's claim 1?	5	Q. (As read):			
	6 A. Yes.	6	"the computer system has a processor			
	Q. You just told us that the method of the	7	coupled to nontransitory memory"			
	8 invention involves performing assembly only on a	8	You see that?			
	9 group of reads that come from a specific region in	9	A. Yes.			
1	0 the target genome.	10	Q. (As read):			
1	1 Where is that in claim 1? Where does it	11	"to perform the steps of: assembling a			
1	2 tell us that?	12	contig from at least some of the plurality of			
1	3 MR. PEPE: Object to form.	13	sequence reads."			
1	4 A. I don't know that I said that that	14	A. Right.			
1	5 that's something that we did when we implemented	15	Q. You see that there?			
1	6 it. Right.	16	So let's let's talk about that.			
1	7 Q. Okay.	17	We agree that not all of the reads need to			
1	8 A. And what it's saying here again I'm	18	find their way into the contig. The contig can be			
	9 no I'm not a patent attorney; so I could be		assembled from at least some of the raw reads;			
	0 wrong, but when we say inputting a reference genome	20	correct?			
2	1 in a plurality of sequencing reads, that doesn't	21	MR. PEPE: Object to form.			
10	2	22	A 337 11 d T' 4 4 d ' d 4 d			

A. Well, the way I interpret this is that the

23 assembly doesn't need to be performed using all of

22

25

24 the reads.

Q. Okay.

24

25 pieces.

22 mean that every read that was generated by the

Q. All right. So let's -- let's take that in

23 sequencer has to be assembled together.

CONFIDENTIAL

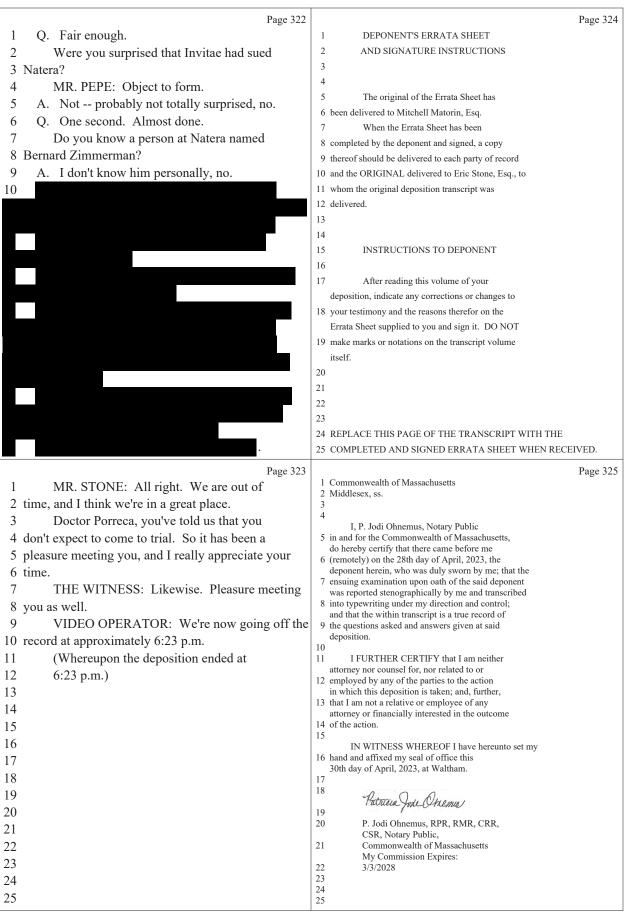


EXHIBIT 3

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

INVITAE CORPORATION,)	
)	
Plaintiff,)	Case No. 21-cv-669-GBW
)	HIGHLY CONFIDENTIAL -
V.)	ATTORNEY'S EYES ONLY
)	
NATERA, INC.)	
)	
Defendant.)	
)	
)	
INVITAE CORPORATION,)	
)	Case No. 21-cv-01635-GBW
Plaintiff,)	HIGHLY CONFIDENTIAL - ATTORNEY'S EYES ONLY
)	
V.)	
)	
NATERA, INC.)	
)	
Defendant.)	
)	

OPENING EXPERT REPORT OF MICHAEL METZKER, PH.D. REGARDING INVALIDITY OF U.S. PATENT NOS. 10,604,799; 11,155,863; AND 11,149,308

- 185. Craig (2008)³⁹⁷ describes a generalized framework for multiplexed resequencing of targeted regions of the human genome on the Illumina Genome Analyzer using degenerate indexed DNA sequence barcodes ligated to fragmented DNA prior to sequencing.³⁹⁸
- 186. Craig (2008) describes attaching barcode sequences to template nucleic acid and assigning the reads to subsets based on the barcode sequences, including attaching barcode sequences to template nucleic acid during sequencing so that multiple samples can be sequenced at once and then demultiplexed, meaning the resulting sequence reads can be grouped by the samples from which they were generated.³⁹⁹

O. Wiseman (2009)

- 187. Wiseman (2009)⁴⁰⁰ describes pyrosequencing of complementary DNA–PCR amplicons as a general approach to determine specific genotypes in in nonhuman primates.⁴⁰¹
- 188. Wiseman (2009) describes grouping reads into subsets based on their barcode sequences and assembling contigs using those barcodes.⁴⁰²

IX. SECTION 101 Analysis

- 189. Counsel have informed me that there is a two-step test for distinguishing patent claims that claim patent-ineligible laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. Step One asks whether the patent claims are directed to ineligible subject matter. If the claims are drawn to ineligible subject matter, then at step two the question is whether the claims include an inventive concept sufficient to transform the claim into a patent-eligible application. Where the additional features recite nothing more than well-understood, routine, or conventional activity, the patent claims directed to an ineligible subject matter remain patent-ineligible. I have also been informed and understand that the typical question at Step One for computer-related claims is whether the claims are directed to an improvement to computer functionality versus being directed to an abstract idea.
- 190. I have been asked to analyze whether the asserted patent claims satisfy the requirements for patentability under 35 U.S.C § 101.

A. Invalidity of the '799 Patent Under Section 101

- 191. In my opinion, the Asserted Claims are directed to an abstract idea, and do not add anything more than well-known, routine, and conventional steps to that abstract idea.
- 192. In particular, the Asserted Claims are directed to the abstract idea of organizing and comparing genomic data. These data are derived from sequencing biological material, which is then translated into data and analyzed within a computer. The methods for organizing

³⁹⁷ Produced as NTRA-INVT-00001151.

³⁹⁸ See Craig (2008) at 887.

 $^{^{399}}$ Id.

⁴⁰⁰ Produced as NTRA-INVT-00001151.

⁴⁰¹ See Wiseman (2009), produced as NTRA-INVT-00009951, at 1322.

⁴⁰² *Id.* at 1322, 1327.

and comparing genomic data recited in the Asserted Patents could even be done by hand or visually, although doing so would not be practically feasible given the sheer volume of data obtained in genomic bioinformatic methods. For example, one could use an integrative genomic viewer ("IGV") to visually inspect how and where sequences of genomic data differ. The Asserted Patents identify this method as being within the prior art. 404

- 193. The claimed methods themselves simply recite a particular algorithm—a compilation of steps—for carrying out the claimed methods for organizing and comparing genomic data. The claims do not recite unique technological hardware or software for carrying out this algorithm, and the results obtained from the algorithm for organizing and comparing the data are inherent in the properties of the biological material that is sequenced or used to create the reference genome. For example, whether any mutations or differences between two sequences are present is due not to the algorithm but to whether biological material itself contains a mutation or errors due to the sequencing process.
- 194. I also understand that the Court made a ruling early in this case where it held that Claim 1 of the '799 patent, as being representative of the asserted patent claims for purposes of analyzing Section 101, was not directed to an abstract idea at Step One, but rather "to a specific solution to a technological problem in the field of sequence assembly. The claimed process enables the identification of mutations with positional accuracy in a computationally tractable manner."⁴⁰⁵
- 195. I respectfully disagree with the Court's assessment. In my opinion, the Asserted Claims merely use the computer as a tool to implement an abstract idea, rather than being directed to a technological improvement itself. Facts now in evidence that were not available to the Court at the time, including deposition testimony of a named inventor of all three Asserted Patents, Dr. Gregory Porreca, and Invitae's bioinformatics scientists, Dr. Joshua Paul and Dr. Andrea Velenich, support my opinion that the Asserted Claims are not directed to eligible subject matter. Dr. Porreca testified that the invention claimed in the Asserted Patents is "an algorithm for making genotype calls" that could be used with "commercially available genotyping software." In other words, the '799 Patent claims merely recite applying algorithms to two data sets in order to obtain a new form of that same data. Dr. Joshua Paul, who is the former Head of Bioinformatics at Invitae, testified that that the method described in the Asserted Patents to combine outputs of two sets of alignments (contigs:reference and reads:contigs to yield reads:reference) was "a high level, philosophical approach to the problem" and that the method, as described, was not "sufficiently specific to make any assessment on what the outcome would be."407 Dr. Andrea Velenich, who is a Principal Bioinformatics Scientist at Invitae, testified that the Asserted Claims contain only "a very high-level description of the method" for the claimed invention. 408

⁴⁰³ See Robinson et al., Integrative genomics viewer, NATURE BIOTECHNOLOGY 9:24-26 (2011) ("Robinson (2011)")

⁴⁰⁴ E.g., '799 Patent at 20:22–31; Robinson (2011).

⁴⁰⁵ D.I. 128 at 4.

⁴⁰⁶ Porreca Dep. Tr. at 57:3–58:2; see also id. at 66:12–70:4; 92:24–97:19, 110:1–137:16.

⁴⁰⁷ Paul Dep. Tr. at 66:21–67:10, 67:20–68:3.

⁴⁰⁸ Velenich Dep. Tr. at 95:3–95:9.

196. In fact, the claimed method could be and was performed manually, such as in Morin (2011) Supplemental Information:

Reads from the individual RNA-seq libraries were assembled using ABySS as previously described using multiple values of k. Iterative pairwise alignments of the contigs from the individual kmer assemblies resulted in a merged contig set that was aligned against the reference Human genome (hg18) using BLAT as described. Putative fusions were identified from contigs that had alignments to two distinct genomic locations. The putative events were filtered using evidence from alignment of reads to contigs using Bowtie and alignments of reads to the genome using BWA. Those events with at least four read pairs from the reads-to-genome alignment and two supporting reads from the reads-to-contig alignment (i.e., across the fusion breakpoint) were manually curated to produce a final list of putative fusions. The genomic breakpoints for the transcriptome predicted events were identified manually from the alignments of the reads to the genome using IGV. The genomic breakpoints were later confirmed by assembly using AbySS and these results are summarized in Supplementary Table S3.

Putative indels were identified from alignment of the contigs to hg18 using BLAT when contiguous unmatched base(s) were found in either the contig (insertion) or reference (deletion) sequences. The events were filtered for read support with events requiring three or more reads to be considered in the filtered set. The filtered set was then screened against dbSNP130 to find putative novel events. The resulting set was manually inspected using read alignments (against both the genome and contigs) to visually confirm candidates. This approach revealed the deletion in GNA13 shown in Supplementary Figure. S4.

The splicing alterations in MLL2 (Fig. 3B and C) and GNA13 (Supplementary Figure S4) were identified from pairwise alignments of the contigs to hg18 using BLAT. The contig alignments were then matched against the four known gene models to identify novel splice junctions. The putative novel splice junctions were filtered where two or more reads were required across the novel junction for the event to be considered. Manual inspection using read alignments (against both the genome and contigs) was performed to visually confirm candidates. 409

- 197. Morin (2011) Supplemental Information discloses the steps of assembly, alignment, and combining information from alignments to identify putative mutations, as described *supra* at Section VIII.H. Morin (2011) Supplemental Information discloses manually performing the step in which mutations are identified and genotyping is performed: "The resulting set was manually inspected using read alignments (against both the genome and contigs) to visually confirm candidates. This approach revealed the deletion in GNA13 shown in Supplementary Fig. S4. . . . Manual inspection using read alignments (against both the genome and contigs) was performed to visually confirm candidates."⁴¹⁰
- 198. As Morin (2011) Supplemental Information demonstrates, the final "combining" step of Claim 1 of the '799 Patent could be and was performed manually. Morin (2011)

⁴⁰⁹ Morin (2011) Supplemental Information at 13–14 (internal citations omitted) (emphases added).

⁴¹⁰ *Id*.

discloses that once one has obtained an assembled contig, a contig:reference alignment, and read:contig alignments, all of which, the Asserted Patents explain, are done using prior-art methods, one could simply look at each alignment and compare them to one another to identify the variants as they exist in the reads relative to the reference genome. The alleged inventors of the Asserted Patents have done nothing more than claim an automated version of a simple visual comparison of data. As discussed supra, merely applying a generic computer to the patentineligible abstract idea of data manipulation does not render the claimed invention patenteligible. This supports my opinion that the Examiner's withdrawal of the rejection of the '891 Application under Section 101 was mistaken. While the Applicant argued to the Examiner the impossibility of assembling and comparing millions of reads by hand, Invitae argued to the court, and the court agreed, that the claims encompass assembly and alignment of just two reads.⁴¹¹ Further, under the Court's claim construction, the claimed method covers any "plurality of sequence reads,"412 i.e., even a very small number of reads. It is my opinion that the computational steps of the claimed method can be performed manually, without a computer, if the number of sequence reads is small enough. As an example, if the "plurality of sequence reads" includes only a few reads, one of ordinary skill in the art would have known how to perform the steps of the claimed method by hand, without the use of a computer, which supports my opinion that the addition of the use of a computer to the claimed method did not render the claims patent-eligible.

- 199. The prosecution history of the Asserted Patents also supports my opinion that the claims are directed to an abstract idea. The Examiner rejected the claims for non-statutory double-patenting over U.S. Patent Nos. 8,209,130 ("'130 Patent") and 8,738,300 ("'300 Patent"). In response, rather than contending that the Asserted Patents are patentably distinct from those two prior patents, the Applicant filed a terminal disclaimer. 414
- 200. The only difference between the independent claims of the '130 Patent and the '799 Patent is that the Applicant added limitations requiring that the claimed method be performed using a generic computer. By issuing a non-statutory double patenting rejection, the Examiner made the determination that the performance of the claimed method using a computer was an obvious variation of the algorithm itself, *i.e.*, the computer requirements do not add any patentable weight to the claim. This further supports my opinion that the District Court wrongly determined that the Asserted Claims of the '799 Patent are patent eligible. In my opinion, it cannot be the case that the alleged invention improves the functioning of a computer itself, if the performance of the claimed invention using a computer is patentably indistinct from the performance of the claimed invention without the use of a computer. This opinion is further supported by the fact that Dr. Porreca himself testified that the Asserted Patents, as well as the '130 Patent, are all "versions of the GATA algorithm," and that "they're all reflecting the same underlying idea." 415
- 201. Further, I have reviewed the Asserted Patents, their common specification, and the prosecution history of the patents, and I do not find any support for the alleged improvement

⁴¹¹ *Id.* at Invitae0000002461–0000002465; D.I. 84 at 16–19.

⁴¹² '799 Patent, Cl. 1.

⁴¹³ See Invitae0000000001 at Invitae0000002450, 2454–2455.

⁴¹⁴ *Id.* at Invitae0000002335.

⁴¹⁵ Porreca Dep. Tr. at 158:1–159:8.

in computational tractability provided by the Asserted Claims. For example, the Asserted Claims themselves do not recite any precise methods for how sequences should be assembled or aligned against each other. Even at the outset of the claims, where some or all of the sequence reads are to be assembled into contigs, the claims do not explain what methods, mathematics, or algorithms should be used to determine precisely which reads should be assembled into contigs. Such precise detail would, at a minimum, be a necessary (but not sufficient) requirement for a process that "enables the identification of mutations with positional accuracy in a computationally tractable manner." Further, I have found no evidence to support the assertion that the claimed methods provide for a more computationally tractable method for assembling sequences. The claims on their face and in light of the specification simply reflect the abstract idea of how genomic data can be organized and compared. Any potential benefit of greater positional accuracy or computational tractability is entirely hypothetical and would, at best, be due to the abstract idea reflected in the claims itself, rather than any claim elements related to how this abstract idea-algorithm is applied or implemented in a computer. The testimony of Dr. Porreca supports my opinion that the Asserted Claims do not claim any improvement in computational tractability. Dr. Porreca testified that when the assembly is performed on "the group of reads that came from a specific region in the target genome," the user is "able to limit the amount of computation that's required to perform the assembly,"416 but the Asserted Claims do not require that the assembly be performed only on a group of reads from a specific region in the target genome. Rather, the Asserted Claims require only "assembling a contig from at least some of the plurality of sequence reads."⁴¹⁷ In other words, Dr. Porreca's assertion about what makes the claimed method more computationally tractable than methods in the prior art is nowhere in the Asserted Claims.

202. The Patent Office examiner rejected draft claims that set forth special hardware or software for carrying out the claimed methods on the basis that these claims were not supported by the written description for the patents. I believe this is further evidence of the fact that, even to the extent the Asserted Claims in theory enable greater positional accuracy or computational tractability, that property is not a technological improvement but simply a theoretical efficiency of the algorithm itself. There is no data or evidence in the Asserted Patents, or in the record of this case as far as I am aware, that the claimed methods of the Asserted Patents, without more, result in an improvement to computer functionality. The Asserted Patents also repeatedly make reference to the use of well-known, prior art methods for performing each of steps of the claimed algorithm. The Examiner eventually withdrew the Section 101 rejection on the ground that the claimed method could not be performed in the human mind. In my opinion, the Examiner was mistaken, because the Asserted Claims merely use the computer as a tool to implement an abstract idea, which could be performed manually, such as through comparing sequences by manual inspection, as described *infra*.

203. In my opinion, nothing significantly more is claimed in the Asserted Patents because the Asserted Claims do not recite any inventive concept that is not an abstract idea. The '799 Patent admits that every other feature of the claimed method other than the abstract idea

⁴¹⁶ Porreca Dep. Tr. at 141:3–142:20.

⁴¹⁷ '799 Patent, Cl. 1.

⁴¹⁸ See Invitae0000000001 at Invitae0000002450, Invitae0000002454– Invitae0000002455.

⁴¹⁹ *Id.* at Invitae0000002477.

itself was well understood, routine, and conventional. Aside from the algorithmic steps of assembling, aligning, and combining data, the only limitations left are "obtaining" a sample comprising DNA and "sequencing" the DNA to generate the sequence reads. Therefore, the '799 Patent merely claims an abstract idea applied to well understood, routine, and conventional elements.

- 204. The '799 Patent specifies that both of the steps of "obtaining" a sample comprising DNA and "sequencing" the DNA to generate sequence reads were conventional and well known in the art. The '799 Patent describes that it was well-understood in the prior art how to obtain a DNA sample, and does not purport to improve on the prior art in this regard. The '799 Patent also states that DNA-sequencing can be accomplished "by any method known in the art," and recounts the many established DNA-sequencing techniques that could be employed to practice the claims, while not purporting to have advanced that prior art at all. The Asserted Claims do not explain or show how sequence data comparison is improved, except by using already-existing computer and sequencing technology.
- 205. The '799 Patent states that sequence reads and a reference genome are input into an standard, general-purpose computer system, 423 to perform the steps of:
 - a. assembling a contig from at least some of those sequence reads, using any method known in the art⁴²⁴;
 - b. aligning the contig to the reference genome to create contig:reference descriptions of mutations, "using any suitable computer program known in the art," 425;
 - c. aligning the sequence reads to the contig using methods known in the art to create read:contig descriptions, ⁴²⁶; and
 - d. combining the contig:reference "descriptions" with the read:contig "descriptions" to produce read:reference "descriptions," to map positional and variant information of mutations found in the individual reads relative to the reference genome. 428
- 206. As the Asserted Claims read in light of the specification demonstrate, all of the methods described in the specification for obtaining a DNA sample, sequencing the DNA, assembling the DNA into contigs, aligning the contigs to the reference genome, aligning the sequence reads to the contig, and describing positional and variant information produced by performing a DNA alignment are routine and conventional methods that were well understood in

⁴²⁰ E.g., '799 Patent at 5:60–63; 6:16–18, 6:30–36,

⁴²¹ '799 Patent at 9:56.

⁴²² *Id.* at 9:56–67: 10:5–12:23

⁴²³ '799 Patent at 2:65–3:42, 12:33–34, FIG. 2.

⁴²⁴ *Id.* at 13:4–16:29, FIG. 1 (step 105), FIG. 2 (step 1)

⁴²⁵ *Id.* at 19:11–13; *see also id.* at 16:54–17:3, 20:35–39, FIG. 1 (steps 109, 113), FIG. 2 (step 2).

⁴²⁶ *Id.* at 20:54–21:11, FIG. 1 (step 117), FIG. 2 (step 3)

⁴²⁷ *Id.* at 21:18–21, FIG. 2 (step 4),

⁴²⁸ *Id.* at 21:22–24; see generally '799 Patent, Cl. 1; '863 Patent, Cl. 1; '308 Patent, Cl. 1, 20.

the art.

- 207. The '799 Patent allegedly teaches a novel choice of which data to compare and the order in which to compare them. The other steps of the method described in the patent are well understood, routine, and conventional, as the '799 Patent explicitly directs the skilled artisan to use unimproved, prior-art DNA sequencing equipment to determine the nucleotide sequence of the sample, and to use unimproved, prior-art hardware and software to generate sequence reads and contigs and to align them to the reference genome. The only thing allegedly new is the abstract idea of the order in which to compare those data.
- 208. Even if the Asserted Claims achieved the purported solution of providing a novel choice of which data to compare and the order in which to compare them, the Asserted Claims only use generic functional language to do so and require nothing other than conventional computer and network components operating according to their ordinary functions (*e.g.*, "a computer processor," "a computer program," "any traditional assembly algorithm," etc.).
- 209. Although the Asserted Claims include "parameters," the claims fail to specify precisely what the parameters *are*, and the parameters at most concern abstract data manipulation—alignment of DNA sequences relative to one another. The '799 Patent itself confirms that the invention is meant to utilize "existing computer power," and nothing in the Asserted Claims, understood in light of the specification, requires anything other than off-the-shelf, conventional computer, sequencing, assembly, and alignment technology and algorithms for performing comparisons between sequence data and presenting the desired information.
- 210. In my opinion, the dependent Asserted Claims are also ineligible for patenting. The dependent Asserted Claims all proceed from the same abstract idea: an algorithmic method of manipulating and combining genetic sequence data using an intermediate data set.
- 211. The dependent Asserted Claims all recite the same well understood, routine, conventional steps of obtaining a DNA sample and sequencing it. The dependent Asserted Claims also all require a generic computer to perform the algorithmic method. Some of the Asserted Claims specify a particular prior-art DNA-sequencing technique, ⁴³⁰ and/or math or algorithm, which is itself an abstract idea, ⁴³¹ or require the identification of one or more naturally occurring mutations based on the math work. ⁴³² Neither the Asserted Claims nor the specification explain what the claimed parameters are or how they should be manipulated, and do not appear to be more than manipulating data in such a way that is abstract. ⁴³³
- 212. None of the dependent Asserted Claims adds an inventive concept because the dependent Asserted Claims do nothing more than limit the application of the abstract idea to specific conventional, routine operations, which does not render the dependent Asserted Claims patent-eligible. Therefore, for the same reasons why Claim 1 of the '799 Patent is directed to patent-ineligible subject matter, the dependent Asserted Claims are also directed to a patent-

⁴²⁹ '799 Patent at 4:52–57.

^{430 &#}x27;799 Patent, Cl. 2–5, 13, 14.

^{431 &#}x27;799 Patent, Cl. 3, 4, 6, 7, 15, 16.

⁴³² '799 Patent, Cl. 8–12.

⁴³³ '799 Patent, Cl. 15–16.

ineligible abstract idea.

213. Thus, it is my opinion that the Asserted Claims of the '799 Patent do not claim a patent-eligible invention. The inventors of the '799 Patent claim to have discovered that information from DNA datasets—reads and contigs—can be compared and combined using existing, prior-art computers and software into a new form that is better than prior-art analyses. That is not a patentable invention. It is, at best, an improved abstract idea. It is my opinion that nothing about the patent claims adds an inventive concept sufficient to save the claims.

B. Invalidity of '308 and '863 Patents Under Section 101

- 214. The '863 and '308 Patents—both continuations of the '799—largely repeat the limitations of the '799 Patent claims. It is my understanding that the parties agree that Claim 1 of each of the '799, '308, and '863 Patents are representative.⁴³⁴
- 215. It is my opinion that the Asserted Claims of the '308 and '863 Patents have the same patent-eligibility problems as the '799 Patent described *supra*.
- 216. Like Claim 1 of the '799 Patent, the independent Asserted Claims of the '308 and '863 Patents are generally directed to methods of organizing and comparing genomic data using a computer. The additional limitations and dependent Asserted Claims in the '308 and '863 Patents are also ineligible for patenting. The Asserted Claims all proceed from the same abstract idea: an algorithmic method of manipulating and combining genetic sequence data using an intermediate data set. The dependent Asserted Claims all recite the same well understood, routine, conventional steps of obtaining a DNA sample and sequencing it. And the dependent Asserted Claims all require a generic computer to perform the algorithmic method.
- 217. Some of the additional limitations and dependent Asserted Claims recited in the '308 and '863 Patents specify a particular prior-art DNA-sequencing technique and/or algorithm, which is itself abstract⁴³⁵), or require the identification of one or more naturally occurring mutations based on the math work. But none of additional elements or dependent Asserted Claims them adds an inventive concept. Rather, the dependent Asserted Claims do nothing more than limit the application of an abstract idea to specific conventional, routine operations. For the same reasons that the independent Asserted Claims of the '308 and '863 Patents are directed to a patent-ineligible abstract idea, the dependent Asserted Claims are also patent-ineligible.
- 218. It is my opinion that, like the Asserted Claims of the '799 Patent, the Asserted Claims of the '308 and '863 Patents merely recite methods for analyzing and comparing digital information extracted from DNA, which is an abstract idea. The purported novelty of both the '308 and '863 Patents remains aligning contigs to the reference genome and reads to contigs. There is no change to either (a) the basic steps of obtaining a DNA sample, sequencing it, and inputting sequence data into a computer, or (b) assembling the reads into contigs, aligning the contigs to the reference genome, aligning the reads to the contig, and combining these two alignments. No new laboratory processes for preparing the genetic sample for analysis are claimed, and no new, unconventional, or non-routine steps are claimed to perform the

⁴³⁴ See Case No. 1:21-cv-00669, D.I. 1, ¶ 15; Case No. 1:21-cv-01635, D.I. 1, ¶¶ 16–17.

^{435 &#}x27;863 Patent, Cl. 2–6, 9; '308 Patent, Cl. 2–4, 15–19.

^{436 &#}x27;863 Patent, Cl. 7, 8; '308 Patent, Cl. 5–14.

computerized analyses. The only differences between the independent Asserted Claims of the '308 and '863 Patents and Claim 1 of the '799 Patent are (i) the addition of prior-art steps in the sequencing process and (ii) superficial elaboration on the ineligible abstract idea at the core of the '799 Patent claims.

- 219. The Asserted Claims of the '308 and '863 Patents do not add anything to render the claimed inventions any more patent-eligible. The Asserted Claims each add limitations that fall into three categories, none of which can confer patent eligibility: (i) limitations that are known in the art according to the patents' common specification, i.e., methods for sequencing DNA, methods for sequencing DNA, 437 methods for aligning those sequences, 438 and methods for storing those alignments on a computer; 439 (ii) additional abstract ideas, *i.e.*, specific mathematical algorithms for analyzing the sequences; and (iii) both natural phenomena and elements known in the art, i.e., types of genetic material to analyze and types of mutations to detect.
- None of the limitations added by the Asserted Claims of the '308 and '863 Patents transforms the claims into an improvement to computer functionality. Adding prior-art limitations on how to prepare the DNA for sequencing (the "attaching the fragments . . ." and "amplifying . . ." limitations) do not qualify as a technological improvement and are conventional and routine. 440 The data comparison methods claimed are nothing but unpatentable abstract ideas.
- The Asserted Claims of the '308 and '863 Patents do not recite any improvement 221. in the functionality or operation of a computer, but instead involve using prior-art, unimproved hardware and prior-art, unimproved software and invoke generic computers as tools.⁴⁴¹ limitations added by the Asserted Claims of the '308 and '863 Patents do not alter the claims' essential character of using a computer as a tool to perform an abstract idea. The Asserted Claims do not change or improve anything about the computer itself, the dependent Asserted Claims simply include more detail on what the user instructs the generic computer to do.
- Instead of identifying a potentially patentable specific improvements in the capabilities of a computer, the '863 Patent identifies only a desirable result or function that can be achieved using existing computers. The Asserted Claims do not describe improvements to the way computers store information or otherwise function, but instead merely rely on their ordinary storage and transmission capabilities and apply that ordinary functionality in the specific context of comparing sequence data. Thus, even if the data comparisons of the '863 Patent had the incidental benefit of freeing up the prior-art computer processor to perform more computations, that would not make the data comparison itself anything other than an unpatentable abstract idea.
- No other limitations—individually or as an ordered combination and apart from those embodying the ineligible subject matter itself—establish an inventive concept that transforms the abstract idea into patent eligible subject matter. The alleged invention of

^{437 &#}x27;799 Patent at 9:56–67; 10:5–12:23.

⁴³⁸ *Id.* at 19:11–20:21

⁴³⁹ *Id.* at 20:43–48.

⁴⁴⁰ E.g., '308 Patent at 15:11–16:32; 17:65–18:64; 19:12–20:23; 21:36–22:16.

^{441 &#}x27;308 Patent at 13:23–16:38; 16:56–20:32; 20:50–64; '863 Patent at 13:26–16:34; 16:59– 20:27; 20:49-56.

combining the contig-based sequence assembly approach with an individual alignment base sequence assembly approach is the abstract idea at the core of the alleged invention.

- 224. The additional limitations found in the Asserted Claims of the '308 and '863 Patents merely describe well understood, routine, and conventional elements and techniques. Indeed, the other steps of the method are well understood, routine, and conventional, as the '308 and '863 Patents explicitly direct the skilled artisan to use unimproved, prior-art DNA sequencing equipment to determine the nucleotide sequence of the sample, and to use unimproved, prior-art hardware and software to generate sequence reads and contigs and to align them to the reference genome. Like for the '799 Patent, the only thing allegedly new that is claimed in the '308 and '863 Patents is the abstract idea of the order in which to compare those data.
- 225. Aside from the algorithmic steps of assembling, aligning, and combining data, the only limitations left are "obtaining" a sample comprising DNA and "sequencing" the DNA to generate the sequence reads. But the '308 and '863 Patents admit that both of those steps were conventional and well known in the art. The '308 and '863 Patents devote over a column of text to recycling the prior art about how to obtain a DNA sample, 442, and do not purport to improve on the prior art in this regard. Likewise, the shared Asserted Patent specification states that DNA-sequencing can be accomplished "by any method known in the art," 443 and recounts the many established DNA-sequencing techniques that could be employed to practice the claims, 444 while not purporting to have advanced that prior art at all.
- The added limitations found in the Asserted Claims of the '308 and '863 Patents add superficial elements to the algorithmic steps of the '799 Patent's process, but, as discussed supra, the common specification acknowledges that these elements, too, are routine and conventional.
- The '308 Patent adds no new elements outside the limitations describing the analysis of digital information. The Asserted Claims simply repackage the invention of the '799 Patent, adding only statistical formulae—i.e., a token elaboration on the ineligible abstract idea itself. See '610 application.
- 228. The '863 Patent adds, in Claim 1, (i) "amplifying the attached fragments to create clusters, each cluster comprising a plurality of copies of the template nucleic acid in one of the channels in the flow cell" and (ii) "attaching the fragments to a surface of channels in a flow cell." But, these elements are routine and conventional and add nothing inventive to the claimed invention.445

⁴⁴² E.g., '799 Patent at 5:60–63, 6:16–18, 6:30-36; '308 Patent at 5:60–63; 6:16–18, 6:30-36;

^{&#}x27;863 Patent at 5:60–63, 6:16–18

⁴⁴³ *Id.* at 9:56

⁴⁴⁴ E.g., id. at 9:56–67; 10:5–12:23

^{445 &#}x27;587 Appl., ¶ 37 ("The amplification reaction may be any amplification reaction known in the art that amplifies nucleic acid molecules, such as polymerase chain reaction, nested polymerase chain reaction, polymerase chain reaction-single strand conformation polymorphism, ligase chain reaction.") (emphasis added); '587 Appl., ¶ 53 ("Another example of a sequencing

229. For at least these reasons, it is my opinion that all of the Asserted Claims are directed to an abstract idea and do not add an inventive concept.

X. SECTIONS 102 AND 103 ANALYSIS

- 230. In **Appendix A**, I set forth a chart showing the references and combinations of references for each of the Asserted Claim. My analysis of those references and combinations is below.
- 231. As I state throughout my Report, I believe the written description of the Asserted Patents and their prosecution histories support my opinions about the invalidity of the Asserted Claims, and I cite to them as part of my analysis. These citations and analysis are not meant to suggest that it is my opinion that the disclosures of the Asserted Patents, and their prosecution histories, themselves would provide one of ordinary skill in the art with a particular motivation or reasonable expectation of success in achieving the claimed invention based on the prior art. As I discuss throughout my Report, the prior art itself provides such motivations and reasonable expectation of success. However, the Asserted Patents provide additional support for my opinions that one of ordinary skill would have had, based on the prior art, the pertinent motivations, as well as knowledge, disclosures, and basis, for forming a reasonable expectation of successfully achieving the claimed invention, and I believe that one of ordinary skill would have applied that existing knowledge within the context of developing a sequence assembly and alignment process or technique.

A. HaplotypeCaller (2011) Anticipates and/or Renders Obvious All Asserted Claims

- 232. It is my understanding that Invitae accuses Natera's use of an implementation of Mutect2, Sentieon's TNseq software, of infringing the Asserted Claims. 446 I further understand from GATK documentation, Invitae's infringement contentions, and conversations with Dr. Banks and Mr. Poplin that the particular functions Invitae accuses of infringement are the same in Mutect2 and HaplotypeCaller.
- 233. It is my opinion that if Sentieon's alleged implementation of Mutect2 is found to infringe any Asserted Claim, HaplotypeCaller (2011) invalidates that claim because it was invented and used before the earliest alleged priority date of the Asserted Claims, September 27, 2011. I have been informed and understand that a product that would infringe the Asserted Claims if developed after their priority date anticipates the Asserted Claims if developed earlier. My opinions on the invalidity of the Asserted Claims in light of HaplotypeCaller (2011) are consistent with Invitae's infringement contentions. Nothing in this opinion should be construed as any admission or opinion on any issues of infringement.

technology that can be used in the methods of the provided invention is Illumina sequencing. Illumina sequencing is based on the amplification of DNA on a solid surface using fold-back PCR and anchored primers. Genomic DNA is fragmented, and adapters are added to the 5' and 3' ends of the fragments. mDNA fragments that are attached to the surface of flow cell channels are extended and bridge amplified." (emphasis added)).

⁴⁴⁶ See Plaintiff Invitae Corporation's Final Infringement Contentions, dated December 19, 2022 ("Final Infringement Contentions"); see also at Final Infringement Contentions, Appendix A; Final Infringement Contentions, Appendix B; Final Infringement Contentions, Appendix C.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: June 16, 2023

Michael L. Metzker Ph.D.

EXHIBIT 4

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

INVITAE CORPORATION,)	
)	
Plaintiff,)	Case No. 21-cv-669-GBW
)	HIGHLY CONFIDENTIAL -
v.)	ATTORNEY'S EYES ONLY
)	
NATERA, INC.)	
)	
Defendant.)	
)	
INVITAE CORPORATION,)	
)	
Plaintiff,)	Case No. 21-cv-01635-GBW
30 /)	HIGHLY CONFIDENTIAL – ATTORNEY'S EYES ONLY
V.)	ATTORNET SETESONET
)	
NATERA, INC.)	
)	
Defendant.)	
-)	
)	

REPLY EXPERT REPORT OF MICHAEL METZKER, PH.D. REGARDING INVALIDITY OF U.S. PATENT NOS. 10,604,799, 11,155,863, AND 11,149,308

VI. SECTION 101 ANALYSIS

- 32. I have been asked by counsel for Natera to respond to Dr. Krane's opinions about my analysis of the validity of the Asserted Claims under Section 101.⁸⁷
- claims that claim patent-ineligible laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. Step One asks whether the patent claims are directed to an ineligible subject matter. If the claims are drawn to an ineligible subject matter, then at Step Two, the question is whether the claims include an inventive concept sufficient to transform the claim into a patent-eligible application. Where the additional features recite nothing more than well-understood, routine, or conventional activity, the patent claims directed to an ineligible subject matter remain patent-ineligible. I have also been informed and understand that the typical question at Step One for computer-related claims is whether the claims are directed to a technological improvement to the computer functionality extending beyond improving the accuracy of a mathematically calculated statistical prediction, versus being directed to an abstract idea such as simply computerized mathematical calculations.
- 34. I incorporate by reference my analysis of the invalidity of the Asserted Claims under Section 101 from the Metzker Op. Report.⁸⁸ It is my opinion that the Asserted Claims do not satisfy the requirements for patentability under 35 U.S.C. § 101 because the Asserted Claims are directed to an abstract idea, and do not add anything more than well-known, routine, and conventional steps to that abstract idea.

A. Invalidity of the '799 Patent Under Section 101

⁸⁷ See Krane Reb. Report at Section IX.

⁸⁸ See Metzker Op. Report at Section IX.

- 35. Nothing in the Krane Reb. Report alters my conclusion that the Asserted Claims are directed to abstract data manipulation—alignment of DNA sequences relative to one another—using a generic computer and prior art sequencing, assembly, and alignment technology and algorithms to perform comparisons between sequences and present the desired information.⁸⁹
- 36. Dr. Krane and I disagree on the correctness of the Court's prior Section 101 ruling. 90 For the reasons explained in the Metzker Op. Report and herein, I respectfully disagree with the Court's assessment of the validity of the Asserted Patents under Section 101. 91 In particular, additional information, including deposition testimony of one of the inventors and Invitae's claim construction arguments, that was not available to the Court at the time of its Section 101 ruling confirms that the Asserted Claims are directed to an abstract idea (computer data manipulation) for detecting a natural phenomenon (mutations in nucleic acid sequences) using routine and conventional methods, and are therefore invalid under Section 101.
- 37. Dr. Krane contends that the claimed methods could not be performed by hand or visually and asserts that the claimed method has "the benefits of reduced computational requirements and increased accuracy," but never explains what it is about the claimed method that gives it these benefits. ⁹² Dr. Krane also asserts that I stated in the Metzker Op. Report that it is "impossible" to perform the claimed method visually or by hand. ⁹³ Dr. Krane is mistaken. In

⁸⁹ *Id*.

 $^{^{90}}$ See Krane Reb. Report at $\P\P$ 113, 118, 120; see also Metzker Op. Report at $\P\P$ 194–195.

⁹¹ See Metzker Op. Report at ¶¶ 194-195.

 $^{^{92}}$ See Krane Reb. Report at \P 114.

⁹³ *Id.*, citing to the Metzker Op. Report at ¶ 192. Dr. Krane mischaracterizes "impossible" with my statement that "doing so would not be practically feasible."

the Metzker Op. Report, I explained that performing the claimed method by hand with a very large number of reads might "not be practically feasible," not that doing so was impossible. In fact, performing genotyping by visual inspection is possible if the number of sequence reads being compared is small enough. I also explained in the Metzker Op. Report that Morin (2011) performs the "combining" step of the claimed method by visual analysis. ⁹⁴ Dr. Krane misreads Morin (2011), appearing to suggest that Morin (2011) only discloses aligning sequence reads directly to a reference genome, ⁹⁵ but Morin (2011) also discloses the steps of the claimed method. ⁹⁶ That is, Morin (2011) discloses generating a read:reference alignment by first aligning contigs to a human reference genome and also aligning the sequence reads to those contigs, using those alignments to visually confirm candidate indels, as well as performing the other steps of the Asserted Claims. ⁹⁷ My Op. Report, which is incorporated herein by reference, contains my analysis of why, in light of Morin (2011) and the other references I detail therein, the Asserted Claims do not teach a "completely new alignment" over the prior art, ⁹⁸ contrary to Dr. Krane's assertion. ⁹⁹

38. To rebut my analysis concerning whether the claimed method can be performed visually or manually, Dr. Krane asserts that "a POSITA, reading the claims and the specification, would understand the patent claims are not directed to a small set of sequence reads." ¹⁰⁰ I

 $^{^{94}~}$ See Metzker Op. Report at $\P\P$ 196–198.

 $^{^{95}}$ See Krane Reb. Report at ¶¶ 121–122.

⁹⁶ See Metzker Op. Report at Sections IX.A, X.H; see also Morin (2011) Supplemental Information at 13–14.

⁹⁷ *Id*.

⁹⁸ See Metzker Op. Report at Section X.H; see generally id. at Section X.

⁹⁹ See Krane Reb. Report at ¶ 123.

¹⁰⁰ *Id*.

disagree. I note that this also appears to be inconsistent with Invitae's attorneys' arguments during the claim construction proceedings, where Invitae's counsel stated that the Asserted Claims encompass performing the method using any number of sequence reads. 101 Regardless, the Asserted Claims of the '799 Patent do not specify or require a large number of reads, nor do they specify the length of the sequence reads. Moreover, Dr. Krane stops short of asserting that the claimed method improves on the prior art by rendering feasible the alignment of millions of reads. Instead, the Krane Reb. Report asserts that the Examiner correctly allowed the Asserted Claims to issue because "the length of the reference genome" makes it difficult to perform the claimed alignment method by hand. 102 The Krane Reb. Report does not argue that performing the allegedly inventive step of combining contig:reference and read:contig alignment information to yield read:reference alignments is impossible to perform manually, nor can Dr. Krane, because that is exactly what Morin (2011) discloses. 103 Assuming for the sake of argument that Dr. Krane meant that because the length of the reference genome, 104 it is impossible to perform the contig:reference alignment by hand, that does not alter my conclusion that the Asserted Claims are directed to the abstract idea of organizing and comparing genomic data. Fundamentally, what is claimed is still the abstract idea of comparing sequences using a generic computer and prior art sequencing, assembly, and alignment technology and algorithms. Moreover, as acknowledged by the Asserted Patents, it was known in the art to align contigs to a reference

¹⁰¹ See D.I. 72 at 31, 44–45; see also D.I. 84 at 9–10.

 $^{^{102}}$ See Krane Reb. Report at ¶ 124 (citing Invitae000000001–0000002508 at Invitae0000002477).

 $^{^{103}}$ See Metzker Op. Report at ¶¶ 196-198.

 $^{^{104}}$ See Krane Reb. Report at ¶ 124 (citing Invitae000000001–0000002508 at Invitae0000002477).

genome, ¹⁰⁵ and therefore, that limitation cannot provide the inventive concept required under Section 101.

- 39. Further, even if it is the case that performing genotyping visually or manually is more error-prone than doing it with a computer, the proposition that a computer can perform a mathematical operation more accurately than a human can perform the same mathematical operation by hand is not a remarkable proposition. Dr. Krane asserts but does not explain how "[t]he inventions of the Asserted Patents improve the reliability of sequence assembly" as compared with the visual genotyping method used in Morin (2011), other than by employing a generic computer to perform the steps of the claimed method. As I opined in the Metzker Op. Report, applying a generic computer to perform an abstract idea without claiming any technological improvement on the process of comparing sequence alignment information, as the Asserted Patents do, does not render the underlying abstract idea of data comparison patent-eligible. 107
- 40. In response to my analysis that the Asserted Claims do not recite any technological improvement in computational tractability nor precise methods for how sequences should be assembled or aligned against each other, ¹⁰⁸ Dr. Krane asserts that the Asserted Claims need not recite the advantages of the invention in order to be patent-eligible. ¹⁰⁹ I have been informed by counsel and understand that a patent need not recite the advantages of the invention in the claims themselves, but an invention's advantages are distinct from the invention itself,

¹⁰⁵ See '799 Patent at 1:38–2:6.

 $^{^{106}~}$ See Krane Reb. Report at \P 114.

 $^{^{107}}$ See Metzker Op. Report at $\P\P$ 192–193, 195, 201–204, 206–209.

¹⁰⁸ *Id*.at ¶ 201.

 $^{^{109}}$ See Krane Reb. Report at ¶ 126.

which must still pass muster under the two-step inquiry. As described in the Metzker Op.

Report, the problem with the Asserted Claims is not that they fail to recite the advantages of the invention, but rather that the Asserted Claims do not claim an invention that results in an inventive technological improvement over the prior art. Further, Dr. Krane asserts that my analysis "oversimplif[ies] the claimed invention as a combination of alignments," but this contradicts Dr. Krane's own opinions in the sections of his report dealing with the analysis of the Asserted Claims under Sections 102 and 103, wherein he refers repeatedly to the "two-step alignment" of the claimed method as what is missing from the prior art and what makes the Asserted Claims "novel and inventive." Regardless, as I previously explained, merely combining data and presenting it in a different form is not inventive.

41. Dr. Krane and I agree that Dr. Porreca testified that prior art methods can be used to perform certain steps of the claimed methods. ¹¹⁴ The Krane Reb. Report, however, overlooks the importance of Dr. Porreca's testimony that the invention claimed in the Asserted Patents is "an algorithm for making genotype calls" that can be used with "commercially available genotyping software." Dr. Porreca's testimony directly supports my opinion that the Asserted Claims are directed to an abstract idea: an algorithm for obtaining and combining data from two sets of alignments (contigs:reference and reads:contigs) to identify mutations or differences.

See Metzker Op. Report at ¶¶ 195, 202, 220. As I acknowledged in the Metzker Op. Report, the specification of the Asserted Patents does recite the alleged advantages of the invention over the prior art. E.g., '799 Patent at 1:44–67, 2:1–6.

 $^{^{111}}$ See Krane Reb. Report at \P 124.

¹¹² See Krane Reb. Report at $\P\P$ 182, 238, 337, 342, 514, 813, 1022, 1248, 1334.

¹¹³ See Metzker Op. Report at ¶¶ 201–209.

¹¹⁴ See Krane Reb. Report at ¶ 118; Metzker Op. Report at ¶ 195.

 $^{^{115}}$ See Porreca Dep. Tr. at 57:3–58:2; see also id. at 65:12–70:4; 92:24–97:19, 110:1–137:16; Metzker Op. Report at ¶ 195.

Those individual steps can be performed using prior art methods of obtaining a nucleic acid sample, sequencing nucleic acids, assembling the sequence reads, and performing alignments. ¹¹⁶ Rather than identify any supposed technological improvement claimed by the Asserted Patents, the Krane Reb. Report relies on the Court's prior determination that the claims are patent-eligible under Section 101, with which I respectfully disagree. Neither the Court nor Dr. Krane states what the "practical technological improvements" the Asserted Claims recite, ¹¹⁷ because there are none.

algorithm for manipulating sequence data. It is not my opinion that the mere fact that the claims are "algorithmic" necessarily renders them patent-ineligible. To the contrary, I have been informed and understand that the Asserted Claims are patent-ineligible under Section 101 if they are directed to an abstract idea and merely invoke the use of a generic computer without reciting any inventive concept or technological improvement. Here, that abstract idea is an algorithmic method for manipulating sequence data. Invoking a computer as a tool to implement an abstract idea does not render the underlying abstract idea a technological improvement over the prior art, as previously explained. In other words, it is not the quality of the claimed method as being "algorithmic" that renders the Asserted Claims patent-ineligible, but rather that the Asserted Claims are directed to an abstract idea without reciting any technological improvement.

¹¹⁶ See Metzker Op. Report at ¶¶ 195, 204–206.

¹¹⁷ *See* Krane Reb. Report at ¶ 118; D.I. 28 at 6.

 $^{^{118}}$ See Krane Reb. Report to Metzker at $\P\P$ 115, 127.

 $^{^{119}}$ See Metzker Op. Report at ¶¶ 192–193, 195, 201–204, 206–209.

¹²⁰ *See* Metzker Op. Report at ¶¶ 200–202.

43. Dr. Krane seems to suggest that the testimonies of Drs. Paul and Velenich are irrelevant. I disagree. For example, the Krane Reb. Report summarizes Dr. Paul as being "familiar with the high-level operations of how variant callers work, but not the details," ¹²¹ and Dr. Velenich as being "insufficiently familiar with the inner workings of callers such as HaplotypeCaller."122 Based on Drs. Paul and Velenich's testimonies, the Krane Reb. Report asserts that these statements are "an endorsement of the inventiveness of the Asserted Claims" because they understand how the Asserted Claims "work at a high level." ¹²³ The Krane Reb. Report takes these statements out of context. For example, Dr. Krane ignores the fact that Drs. Paul and Velenich were each answering the question of whether the Asserted Claims, as written, contained enough detail for one of ordinary skill in the art to have understood how it works and perform the claimed method. Moreover, Dr. Paul and Velenich each answered that question in the negative. Dr. Paul testified that the Asserted Claims are a "high level, philosophical approach to the problem" for which it would be "a leap" to make "any statement about quality" as an improved method of variant-calling. 124 Dr. Velenich made the same conclusion, testifying that the Asserted Claims were a "high level description of the method" that lacked "implementation details" necessary to perform the claimed method. 125 It is of no matter that Drs. Paul and Velenich testified that they are unfamiliar with the inner workings of different variant callers, particularly in light of the fact that both appear to mee the qualifications of one of ordinary skill in the art under my and Dr. Krane's proposed definitions.

¹²¹ See Krane Reb. Report at ¶ 119, citing to Paul Dep. Tr. at 68:5–19.

¹²² *Id.*, citing to Velenich Dep. Tr. at 93:13–18.

¹²³ *Id.* at ¶ 119.

¹²⁴ See Paul Dep. Tr. at 66:21–67:10.

¹²⁵ See Velenich Dep. Tr. at 94:13–95:8.

- 44. The Krane Reb. Report asserts that "the applicant correctly argued that the sequence reads were transformed by the methods, and thus not an abstract idea." ¹²⁶ Here, the Krane Reb. Report is referencing the file history wherein the Applicant argued that the method transforms sequence reads, which are "not directly readable as the subject's genome" when they come off the sequencer, into something usable, *i.e.*, a contig aligned to a reference genome. ¹²⁷ Dr. Krane ignores that the Court construed the term "sequence reads" to mean "raw reads as generated by the sequencing instrument."128 In fact, the Krane Op. Report argues that Natera infringes the Asserted Claims even though Signatera uses as an input reads that have been prealigned to a reference genome in the form of a BAM file. 129 In light of these statements, it appears that Dr. Krane views the claimed method as the same whether it is performed with reads as they come off the sequencer (i.e., raw reads) or with aligned reads (i.e., pre-processed or prealigned). Yet, the Krane Reb. Report appears to assert that the claimed method "transform[s]" sequence reads in some way. 130 If the use of pre-aligned reads to perform the claimed method is equivalent to the use of sequence reads as they come off the sequencer, it cannot be that the claimed method "transforms" the sequence reads in any manner. This reinforces my conclusion that the Asserted Claims are directed to a patent-ineligible abstract idea of sequence read data manipulation without any technological improvement.
 - 45. The Krane Reb. Report references the prosecution history of the Asserted Claims

¹²⁶ See Krane Reb. Report at ¶ 12.

¹²⁷ See Invitae000000001-0000002508 at Invitae0000002335-0000002338.

¹²⁸ See D.I. 84; D.I. 85.

¹²⁹ See, e.g., Krane Op. Report at ¶¶ 80–87.

¹³⁰ See Krane Reb. Report at \P 12.

to say that finding them valid was a "condition of their issuance." Dr. Krane, however, fails to rebut my analysis concerning how the prosecution history supports my conclusion that the Asserted Claims are not patent-eligible. Further, as discussed in the Metzker Op. Report, the Applicant filed a terminal disclaimer in response to a non-statutory double-patenting rejection over the '130 Patent—showing the Examiner thought the claimed method is nothing more than an obvious variation of the high-level algorithm, to which the computer requirements added nothing of patentable weight—rather than contend the '799 Patent was patentably distinct from the '130 Patent. This demonstrates that the use of a computer added nothing of patentable weight to the Asserted Claims. Dr. Porreca's testimony that the Asserted Patents and the '130 Patent are all "versions of the GATA algorithm" further supports this conclusion, which the Krane Reb. Report does not dispute. 134

46. The Krane Reb. Report also misconstrues my analysis regarding the inherent properties of the biological material. My opinion is that the Asserted Claims are directed to an abstract idea that uses prior art methods to detect mutations or differences that are inherent in the properties of the biological material that is sequenced or used to create the reference genome. Further, it is my understanding that, contrary to the Krane Reb. Report's suggestion otherwise, the Court did not "reject[]" any argument that the Asserted Claims are directed to inherent

¹³¹ *Id.* at ¶ 110.

 $^{^{132}}$ See Metzker Op. Report at ¶¶ 199–200.

¹³³ See Porreca Dep. Tr. at 158:1–159:8.

 $^{^{134}}$ See Metzker Op. Report at ¶ 200.

 $^{^{135}}$ See Krane Reb. Report at ¶ 116.

¹³⁶ See Metzker Op. Report at ¶ 193.

properties of biological material.¹³⁷ As I have been informed by counsel, neither party made such an argument in connection with the Court's earlier decision on Section 101.¹³⁸

47. The Krane Reb. Report simply disagrees with my analysis of the dependent claims "for the reasons stated for the independent claims." Obviously, Dr. Krane does not challenge my conclusions that the dependent claims all proceed from the same abstract idea claimed in the independent claims, also require a generic computer to perform the algorithmic method, and only limit the abstract idea to the use of particular prior art methods. 140

B. Invalidity of the '308 and '863 Patents Under Section 101

- 48. Dr. Krane's cursory rebuttal to my analysis of the invalidity of the '308 and '863 Patents under Section 101 lacks any substantive response to my analysis that the Asserted Claims of the '308 and '863 Patents are directed to an abstract idea and do not recite an inventive concept.¹⁴¹
- 49. In particular, the Krane Reb. Report fails to rebut my analysis demonstrating that nothing about the additional limitations and dependent claims of the 308 and 863 Patents renders them patent-eligible over the 799 Patent. As I explain in detail in the Metzker Op. Report, the additional limitations and dependent claims recited in the 308 and 863 Patents do not add an inventive concept, but rather merely limit the application of an abstract idea to specific conventional, routine operations. Dr. Krane asserts, without elaboration, that "the

¹³⁷ See Krane Reb. Report at ¶ 117.

¹³⁸ See D.I. 28.

¹³⁹ See Krane Reb. Report at ¶ 128.

¹⁴⁰ See Metzker Op. Report at ¶¶ 210–213.

¹⁴¹ See Krane Reb. Report at ¶¶ 130–131.

 $^{^{142}}$ See Metzker Op. Report at ¶¶ 215–229.

¹⁴³ *Id*.

Asserted Claims of the '308 and '863 Patents are, as described for the '799 Patent, patent eligible and do not suffer from any of the alleged shortcomings Dr. Metzker offers in his opinion." Nowhere does the Krane Reb. Report explain why the Asserted Claims of the '308 and '863 Patents "do not suffer from any of the alleged shortcomings" I identified in the Metzker Op. Report or why "the dependent claims do add further inventive concepts." 145

50. In particular, the Krane Reb. Report makes no attempt to respond to my conclusion that the independent Asserted Claims of the '308 and '863 Patents recite the same abstract idea of an algorithmic method of manipulating and combining genetic sequence data. ¹⁴⁶ This is because the independent Asserted Claims of the '308 and '863 Patents do not change the basic steps of the method claimed in the '799 Patent nor recite any new methods of sample preparation or analysis that are unconventional or non-routine steps to perform the computerized analysis. ¹⁴⁷ The Krane Reb. Report does not rebut my conclusion that the only differences between then independent Asserted Claims of the '308 and '863 Patents and the '799 Patent are (i) the addition of prior art methods and (ii) non-substantive elaboration on the abstract idea claimed in the '799 Patent. ¹⁴⁸ Dr. Krane also does not refute that the limitations added in the '308 and '863 Patents merely recite prior art methods of sequencing a nucleic acid sample, aligning those sequences, storing those alignments on a computer, and analyzing those alignments using specific mathematical algorithms, and describe natural phenomena and

 $^{^{144}}$ See Krane Reb. Report \P 131.

¹⁴⁵ Id

 $^{^{146}}$ See Metzker Op. Report at $\P\P$ 215–229.

¹⁴⁷ *Id*.

¹⁴⁸ *Id*.

elements known in the art. ¹⁴⁹ The Krane Reb. Report also does not respond to my conclusion that the added limitations of the Asserted Claims of the '308 and '863 Patents do not claim any improvement to computer functionality but instead recite only conventional and routine steps using prior art, unimproved hardware and prior art, unimproved software invoking generic computers as tools. ¹⁵⁰

- 51. In the Krane Reb. Report, Dr. Krane spends a single sentence responding to my analysis that the dependent Asserted Claims of the '308 and '863 Patents are also patent-ineligible, saying only that "the dependent [sic] claims do add further inventive concepts." 151 The Krane Reb. Report makes no effort to say what "further inventive concepts" Dr. Krane alleges the dependent Asserted Claims of the '308 and '863 Patents add, 152 or to respond to my conclusion that the dependent claims simply add known elements regarding how a generic computer is to perform the claimed method for comparing sequence data without describing any improvements to how a generic computer stores information or functions. 153
- 52. In particular, the Krane Reb. Report does not respond to my conclusion that the dependent Asserted Claims are directed to a patent-ineligible abstract idea because they recite the same well understood, routine, conventional steps of obtaining a DNA sample and sequencing it using conventional, routine, prior art methods, and require a generic computer to perform the algorithmic method.¹⁵⁴ Similarly, the Krane Reb. Report did not respond to my

¹⁴⁹ *Id*.

¹⁵⁰ *Id.* (citing to '308 Patent at 13:23–16:38; 16:56–20:32; 20:50–64; '863 Patent at 13:26–16:34; 16:59–20:27; 20:49–56.).

¹⁵¹ See Krane Reb. Report at ¶ 131.

¹⁵² Id

¹⁵³ See Metzker Opening Report at ¶¶ 215–229.

¹⁵⁴ *Id*.

conclusion that the dependent Asserted Claims of the '308 and '863 Patents do not add an inventive concept because they either (i) merely limit the application of an abstract idea to specific conventional, routine operations using prior art DNA sequencing techniques and/or algorithms or (ii) require the identification of one or more naturally occurring mutations based on mathematical operations. ¹⁵⁵

53. For at least the same reasons I identified in the Metzker Op. Report—reasons that the Krane Reb. Report has done little to refute—it is my opinion that all of the Asserted Claims are directed to an abstract idea and do not add an inventive concept. 156

VII. SECTIONS 102 AND 103 ANALYSIS

54. Nothing in the Krane Reb. Report causes me to change the opinions rendered in the Metzker Op. Report, and I incorporate those opinions herein. In this Section, I address the arguments raised by the Krane Reb. Report, and where Dr. Krane incorporates his analysis of other claims or claim limitations into his analysis of a certain claim limitation, I do, as well. I do not address the invalidity of claim limitations that the Krane Reb. Report does not dispute, as I assume that Dr. Krane agrees with my opinions. My analysis of each independent Asserted Claim applies equally to the claims depending from them. I also note that in several instances, Dr. Krane only opines that certain dependent claims are not anticipated, and does not offer any opinion, or rebuttal to the Metzker Op. Report as to obviousness of those claims. ¹⁵⁷ I therefore understand that Dr. Krane's opinions as to these claims are limited to his opinion that they are not anticipated. However, in the event Dr. Krane provides an opinion as to non-obviousness, I

¹⁵⁵ *Id*.at ¶¶ 216–217, 221.

¹⁵⁶ See Metzker Op. Report at Section IX.

¹⁵⁷ See, e.g., Krane Reb. Report at ¶¶ 624–625, 1042, 1044–1045, 1056–1057, 1249, 1251–1252.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: August 11, 2023

Michael L. Metzker Ph.D.

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

INVITAE CORPORATION,

Plaintiff,

v.

NATERA, INC.

Defendant.

INVITAE CORPORATION,

Plaintiff,

v.

NATERA, INC.

Defendant.

Case No. 21-cv-669-GBW

JURY TRIAL DEMANDED

HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY

Case No. 21-cv-1635-GBW

JURY TRIAL DEMANDED

HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY

REBUTTAL EXPERT REPORT OF DAN E. KRANE TO THE OPENING EXPERT REPORT OF MICHAEL METZKER, PHD

Dated: July 21, 2023

Dr. Dan E. Krane

By: Dan E. Rame

105. Craig (2008) merely discloses using barcodes on fragmented DNA and using the wholly irrelavent Bayes factors. Id. Dr. Metzker's description is very specific and overreaching for the amount of information Craig (2008) actually discloses, those conclusions cannot be drawn from what Dr. Metzker has cited. Metzker Opening Report ¶ 186.

O. Wiseman (2009)

- 106. Wiseman (2009) discloses "pyrosequencing of complementary DNA-PCR amplicons as a general approach to determine comprehensive MHC class I genotypes in nonhuman primates." Wiseman (2009) at 1322.
- 107. Wiseman (2009) discloses using barcoding on amplicons and grouping those amplicons into four sets. Wiseman (2009) at 1322. It also discloses creating contigs from the amplicons, but does not disclose using the barcodes using contig construction. Wiseman (2009) at 1327.

IX. SECTION 101 ANALYSIS

- 108. As discussed in Section V, counsel has informed me and I understand the two-step test for determining patentable claims under Section 101. *See supra* discussion.
- 109. I have been asked to analyze the Asserted Claims as well as Dr. Metzker's analysis.

 Metzker Opening Report ¶¶ 189-213.
- 110. As a preliminary matter, I understand that the Asserted Claims have already been found valid under Section 101 by the USPTO as a condition of their issuance. Further, I also understand that the Court has already ruled once on the validity under Section 101 of Claim 1 of the '799 Patent, as representative of the Asserted Claims, and has also ruled that the Asserted Claims are valid under Section 101.

A. Validity of the '799 Patent Under Section 101

- 111. In my opinion, the Asserted Claims are not directed to an abstract idea, and, regardless, add more than well-known, routine, and conventional steps.
- 112. Specifically, the Asserted Claims are directed to a specific technological problem, that of assembling DNA sequences, and they explain on a specific basis how to solve this problem in a better way than existed in the prior art at the time.
- 113. Having reviewed Dr. Metzker's opinion as well as, with attorney assistance, the Court's earlier Section 101 ruling on Claim 1 of the '799 Patent, I do not believe Dr. Metzker raises any substantive new argument in his opinion that was not already addressed by the Court in its previous ruling, nor do I believe he provides any evidence sufficiently novel to shed a different light upon these already-litigated arguments. I agree with the Court's previous ruling. D.I. 28.
- 114. The Asserted Claims are directed to the concrete steps of sequence assembly, with the benefits of reduced computational requirements and increased accuracy. Dr. Metzker claims that the methods of the Asserted Patents could be done by hand or visually, but then immediately states that this is impossible. Metzker Opening Report ¶ 192. The inventions of the Asserted Patents improve the reliability of sequence assembly, and taking Dr. Metzker's visual approach only introduces more errors into the assembly.
- are invalid upon that basis. Metzker Opening Report ¶ 193. As I have been informed by Invitae's attorneys and as I understand from the Court's previous Section 101 ruling, the mere labelling of something as "algorithmic" does not preclude patent eligibility. D.I. 28 at 6 ("By contrast, here, Claim 1 *not only recites an algorithmic method* of manipulating and combining genetic sequence data..."). Nor does Dr. Metzker's opinion that the claims are invalid for "not recit[ing] unique

"directed to a concrete *technique*" in its prior Section 101 briefing to the Court, and the Court agreed, ruling that the Asserted Claims "recite[] the application of the method." *Id*. at 6.

- 116. Dr. Metzker then opines that the Asserted Claims claim inherent properties of biological material. Metzker Opening Report ¶ 193. As I explain further in Section X, I disagree with this opinion. See infra. The Asserted Patents do not claim the existence of mutations, but rather an inventive and improved method for detecting them. Dr. Metzker's argument here conflates the two issues and amounts to opining that a patent for a new and improved type of microscope for biological samples is actually claiming every disease contained within said biological samples. As discussed throughout this Report, the claimed methods do not merely "organiz[e] and compar[e] genomic data," the claimed methods combine methods for detecting mutations in an inventive manner, creating a new method that decreases computational requirements and increases accuracy.
- 117. Additionally, Dr. Metzker's "inherent properties" opinion has also already been rejected by the Court. In its previous ruling, the Court stated that the invention "is directed to a specific solution to a technological problem in the field of sequence assembly. *The claimed process enables the identification of mutations* with positional accuracy in a computationally tractable manner." D.I. 28 at 4.
- 118. Nor does the deposition testimony of Drs. Porreca, Paul, and Velenich support Dr. Metzker's opinion, contrary to his assertions. Metzker Opening Report ¶ 195. First, his characterization of Dr. Porreca's testimony is incorrect at best. Dr. Porreca does not describe the invention as used with commercially available genotyping software, merely that it could be used *for one particular step*, and that the invention is the entire method, which contains within it some

steps which may be performed by known algorithms. *See, e.g.* Porreca Depo at 57:11-19; 66:12–70:4; 92:24–97:19, 110:1–137:16. This line of argument, too, was already raised by Natera in its prior briefing to the Court, where it argued that the Asserted Claims simply recited "well understood, routine, and conventional elements" already known in the art. D.I. 9 at 11-12. The Court rejected this argument when it ruled that the Asserted Claims were patent eligible, noting that the Asserted Claims "recite applying the new and improved computerized methods to practical technological improvements." D.I. 28 at 6. I see no new justification in Dr. Metzker's report for its reconsideration now.

- 119. Second, Dr. Metzker's citations to the testimony of Drs. Paul and Velenich lack context. Dr. Paul testified that he is familiar with the high-level operations of how variant callers work, but not the details. *See*, *e.g.* Paul Depo at 68:5-19. Thus, his answer that he understands the Asserted Claims to work at a high level which Dr. Metzker cites is in fact an endorsement of the inventiveness of the Asserted Claims to the extent of his ability to answer. Dr. Velenich gives similar testimony that she is insufficiently familiar with the inner workings of callers such as HaplotypeCaller. *See*, *e.g.*, Velenich Depo at 93:13-18.
- Patent claims merely recite applying algorithms to two data sets in order to obtain a new form of that same data." Metzker Opening Report ¶ 195. The Court has already explained the error of this position in its previous ruling, and I see no support cited by Dr. Metzker sufficiently novel to justify revisiting this argument. D.I. 28 at 6 ("When Natera says that the claims before me are directed to *just a mathematical result* or simply involve using computers as tools rather than any improvement in computers or other technology, *I disagree*.")

- 121. Dr. Metzker then references his analysis of Morin (2011). Metzker Opening Report ¶ 196. I discuss Dr. Metzker's analysis of Morin (2011) in Section X.H, and incorporate it by reference here accordingly. *See infra*.
- 122. As shown in the very excerpt of Morin (2011) Supplemental Information quoted by Dr. Metzker, Morin (2011) describes little more than the prior art already acknowledged in the Asserted Patents. For instance, Morin (2011) Supplemental Information discloses read-to-reference alignments as "alignments of reads to the genome using BWA" and "at least four read pairs from the reads-to-genome alignment." Metzker Opening Report ¶ 196. The direct alignment of reads to references to identify mutations is well established prior art as explained in, *inter alia*, the specification of the Asserted Patents themselves, as well as Invitae's prior Section 101 briefing, which the Court ruled in favor of.
- 123. In contrast to Morin (2011), the Asserted Claims teach a new and inventive solution to the problem of sequence assembly involving creating a completely new alignment through the combination of the read:contig and contig:reference alignments. While the comparatively primitive process detailed in Morin (2011) was performed manually, the method of the Asserted Patents cannot be performed in the human mind. Dr. Metzker disagrees, describing a hypothetical (and *purely* hypothetical, for such a project is a gross oversimplification of the problem relative to the practical application of the method to actual sequence reads) project which involves aligning only two sequence reads. Dr. Metzker opines that in such a project, the number of sequence reads is few enough and gives a contig that is short enough that a person could, potentially, align that relatively small amount of nucleotide sequence information in some period of time. Metzker Opening Report ¶ 198. However, a POSITA, reading the claims and the specification, would

understand that the patent claims are not directed to a small set of sequence reads. See, e.g., '799 Patent at 1:28-37, 2:39-43, 9:56-12:23.

- a combination of alignments, as Dr. Metzker has done, as the Examiner noted in the Reasons for Allowance, it is not the number of sequence reads that makes alignment by hand impossible, *it is the length of the reference genome*. Invitae0000002477. Even for the simpliest of organisms such as *E. coli*, its genome contains between 4.5 and 5.5 million base pairs, depending on the strain being considered. For more complex organisms, such as humans, the complexity rises geometrically. For example, human chromosome 21, the *smallest* of the *twenty-three* chromosome pairs in humans and representing a mere 1.5% of the human genome, is an *order of magnitude larger* than the entire *E. coli* genome. As noted by the Examiner and misunderstood by Dr. Metzker, the claimed methods cannot be performed by hand not just because of the number of base pairs one is attempting to align, but because of the number of base pairs one is attempting to *align against*.
- 125. Dr. Metzker proceeds to argue that because Morin (2011) showed the "combining" step could be performed manually, because the '130 and '799 Patents differ only in that the '799 recites the use of a computer, and because the Examiner issued the '799 Patent with a terminal disclaimer, thus the '799 patent must be invalid. Metzker Opening Report ¶ 198-200. However, as demonstrated above, Dr. Metzker's entire argument fails at its first step, as Morin (2011) does not, in fact, show that the methods of the Asserted Patents could be performed manually.
- 126. Dr. Metzker next opines that the "Asserted Claims do not claim any improvement in computational tractability," stating that "the Asserted Claims themselves do not recite any precise methods for *how* sequences should be assembled or aligned against each other." Metzker

Opening Report ¶ 201. However, I understand from the Court's prior ruling that the claims themselves do not need to articulate the advantages of the claimed combinations or of the invention in order to be patent eligible. D.I. 28 at 6 ("We know from cases like *Uniloc*, as well as . . . last week's decision *Mentone Solutions LLC v. Digi International Inc.*, . . . that *the claims themselves* do not need to necessarily articulate the advantages of the claimed combinations or of the invention in order to be patent eligible.") Instead, such articulation may also be found in the specification, drawings, or be inherent in the patent's disclose due to the skill in the art at the time.

- 127. Regarding Dr. Metzker's opinion that "the Asserted Claims merely use the computer as a tool to implement an abstract idea, which could be performed manually, such as through comparing sequences by manual inspection" (Metzker Opening Report ¶ 202) I have already explained his error. *See supra* discussion of Morin (2011). Regarding his opinion that the Asserted Claims are "algorithmic" and thus invalid, as I state *supra*, I understand from from the Court's prior ruling on this topic that something being "algorithmic" does not render it unpatentable.
- 128. Dr. Metzker proceeds to analyze the dependent claims, and opines that they, too, are unpatentable under Section 101. Metzker Opening Report ¶ 204-12. I disagree for the reasons stated for the independent claims.
- 129. It is my opinion that the Asserted Claims of the '799 Patent do claim a patenteligible invention. The inventors of the '799 Patent claim a novel method of sequence assembly that employs a strategy/approach that improves the computational tractability of the problem that cannot be completed by a human mind alone.

B. Validity of '308 and '863 Patents Under Section 101

- 130. The '863 and '308 Patents are continuations of the '799 Patent and share a common specification. It is also my understanding that the parties agree that Claim 1 of each patent is representative, as Dr. Metzker states in his report. Metzker Opening Report ¶ 214.
- 131. It is my opinion that the Asserted Claims of the '308 and '863 Patents are, as described for the '799 Patent, patent eligible and do not suffer from any of the alleged shortcomings Dr. Metzker offers in his opinion. *See supra* analysis. It is my opinion that none of the Asserted Claims are directed to an abstract idea and and the dependant claims do add further inventive concepts.

X. SECTIONS 102 AND 103 ANALYSIS

- 132. I have reviewed the chart provided by Dr. Metzker as Appendix A of his Opening Report.
- 133. I have reviewed Dr. Metzker's opnions in his Opening Report and respectfully disagree. I do not believe the Asserted Claims or the Asserted Patents are invalid. They disclose inventions for sequence assembly and alignments that were novel at the time of the inventions. The Asserted Patents' disclosures, as well as the state of the prior art, show that this is true.

A. HaplotypeCaller (2011) Does Not Anticipate and/or Render Obvious All Asserted Claims

134. Dr. Metzker opines that the asserted claims of the Asserted Patents are anticipated by HaplotypeCaller (2011), or rendered obvious alone or in combination with information known to skilled artisans at the time of the invention and/or other references disclosed in Dr. Metzker's report, as well as common sense and the general state of the art. Metzker Opening Report ¶ 234. I disagree.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY	CORPORATION OF)	
AMERICA HOLI	DINGS,)	
	Plaintiff,)	C.A. No. 21-669 (GBW)
v.)	
NATERA, INC.)	
	Defendant.	<u> </u>	
LABORATORY CORPORATION OF AMERICA HOLDINGS,)	
	Plaintiff,)	C.A. No. 21-1635 (GBW)
v.)	
NATERA, INC.)	
	Defendant.)	

PLAINTIFF'S REPLY IN SUPPORT OF ITS MOTION IN LIMINE NO. 1: TO PRECLUDE NATERA FROM CONTESTING VALIDITY UNDER 35 U.S.C. § 101

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Dated: August 13, 2025

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Attorneys for Plaintiff Laboratory Corporation of America Holdings Natera seeks to introduce evidence regarding patent eligibility of the Asserted Patents under §101 in an effort to persuade the Court to revisit its prior ruling on this issue. Opp. at 1.

As the Federal Circuit explained in *CardioNet, LLC v. InfoBionic, Inc.*, however, "*Alice* step one presents a legal question that can be answered based on the intrinsic evidence" and the Court's "analysis at *Alice* step one involves examining the patent claims in view of the plain claim language, statements in the written description, and the prosecution history, if relevant." 955 F.3d 1358, 1372-73 (Fed. Cir. 2020). This Court was not required to consider other extrinsic evidence at *Alice* step one. And unlike the court in Natera's cited *Smartflash LLC v. Apple Inc.*, once this Court decided Natera failed *Alice* step one, there was no need to proceed to step 2.

Even if the Court were to consider extrinsic evidence, none of the evidence cited in Natera's opposition rises to the level "extraordinary circumstances" that would require this Court to revisit its *Alic*e step one ruling. *See Savvy Dog Sys., LLC v. Pennsylvania Coin, LLC*, No. 3:19-cv-01470, 2022 WL 4349829, at *5 (M.D. Pa. Sept. 19, 2022). Natera's citation to Dr. Porreca's testimony regarding "a computational algorithm" ignores this Court prior ruling that labelling something as "algorithmic" does not on its own preclude patent eligibility. Opp. at 2; D.I. 28 at 6 ("By contrast, here, Claim 1 not only recites an algorithmic method of manipulating and combining genetic sequence data..."). Natera's argument regarding "computational tractability" is similarly unpersuasive as it ignores the Court's prior ruling that the claims themselves do not need to articulate the advantages of the claimed combinations or of the invention in order to be patent eligible. Opp. at 2-3, D.I. 28 at 6 ("We know from cases like *Uniloc*... that the claims themselves do not need to necessarily articulate the advantages of the claimed combinations or of the invention in order to be patent eligible.").

This Court's prior ruling regarding patent eligibility under §101 should be upheld.

August 13, 2025

Respectfully submitted,

FARNAN LLP

/s/ Brian E. Farnan

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CERTIFICATE OF SERVICE

I, Brian E. Farnan, hereby certify that on August 13, 2025, a copy of PLAINTIFF'S REPLY IN SUPPORT OF ITS MOTION IN LIMINE NO. 1: TO PRECLUDE NATERA FROM CONTESTING VALIDITY UNDER 35 U.S.C. § 101 was served on the following as indicated:

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Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 499 of 739 PageID

EXHIBIT 19B

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION OF AMERICA HOLDINGS,)
Plaintiff,) C.A. No. 21-669 (GBW)
V.)
NATERA, INC.)
Defendant.	,)
LABORATORY CORPORATION OF AMERICA HOLDINGS,)))
Plaintiff,) C.A. No. 21-1635 (GBW)
v.	
NATERA, INC.)
Defendant.)

PLAINTIFF'S MOTION IN LIMINE NO. 2: TO EXCLUDE EVIDENCE AND ARGUMENT REGARDING THE PRIOR LITIGATION BETWEEN INVITAE AND NATERA

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Dated: February 9, 2024

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Attorneys for Plaintiff Laboratory Corporation of America Holdings Pursuant to Federal Rules of Evidence 402, 403, and 404, Invitae moves to preclude Natera, from offering prejudicial argument, evidence, or testimony regarding the prior litigation between the parties, namely *Natera, Inc. v. ArcherDX, Inc. et al.*, C.A. No. 20-125-GWB (D. Del.) (the "prior litigation"). This includes, but is not limited to, the outcome of the jury trial or allegations that the instant case is an attempt by Invitae to retaliate against Natera for the prior litigation. Indeed, the unfair prejudice caused by allowing Natera to cast Invitae as engaging in retaliatory litigation would be great and would be counterbalanced by no probative value whatsoever.

While the parties agree that a discrete subset of the damages evidence in the prior litigation may relate to a reasonable royalty analysis in this case, all of the other issues – whether technical, equitable, business, or other – are irrelevant. The limited relevant damages evidence does not require additional surrounding prejudicial context or details to provide its full probative value. Invitae proposed the parties simply refer to the relevant damages evidence as from a previous litigation, without mention of the parties involved or circumstances. But Natera, intent on painting Invitae in a bad light, refused.

I. PRIOR LITIGATION HISTORY IS IRRELEVANT, UNFAIRLY PREJUDICIAL, AND IMPERMISSIBLY GOES TO CHARACTER

As a rule, evidence regarding litigation history and the outcome of previous lawsuits are "generally inadmissible." *Johns Hopkins University v. Alcon Labs. Inc.*, C.A. No. 15-525, 2018 WL 4178159, at 42-43 (D. Del. Aug 30, 2018). Such evidence "has, at best, miniscule probative value, and this is significantly outweighed by the potential for confusion of the issues that would result from admission of the evidence." *10X Genomics, Inc., et al. v. Nanostring Technologies, Inc.*, C.A. No. 21-653-MFK, D.I. 277, at 3 (D. Del. Nov 2, 2023). Even when minimal relevance exists, courts in this district still exclude litigation history evidence "as its probative value is substantially outweighed by the danger of unfair prejudice." *AVM Technologies LLC v. Intel*

Corporation, C.A. No. 15-33-RGA, D.I. 637, at 1-2 (D. Del. Apr. 19, 2017); see also Willis Electric Co., Ltd. v. Polygroup Limited et al., C.A. No. 15-3443 (JNE/DTS), D.I. 930, at 15-17 (D. Minn Jan. 5, 2024) ("Accordingly, Polygroup is precluded from presenting any evidence or argument regarding the prior lawsuits, even if Willis Electric references intellectual property issues, under Federal Rules of Evidence 402, 403 and 404(b)."); Cosmos Granite (W.), LLC v. Minagrex Corp., No. 19-cv-1697, 2021 WL 5140226, at *2 (W.D. Wash. Nov. 4, 2021); CellTrust Corp. v. Ionlake, LLC, No. 19-cv-2855, 2023 WL 3052733, at *4-6 (D. Minn. Apr. 23, 2023).

These cases squarely address the issue Invitae now raises. A few discrete and self-contained facts from the prior litigation, which both parties' damages experts in this case have addressed in their reports, pertain solely to the calculation of a reasonable royalty for damages. This, however, should not open the door to laissez-faire presentation of every single scrap of prejudicial evidence or argument regarding the prior litigation, as Natera seemingly contends is warranted. Indeed, Natera's apparent motive for its position, namely a trial strategy centered on depicting Invitae as a vengeful litigator in search of an opportunity to retaliate against Natera for the prior litigation, is, as the above cases show, *precisely* why courts preclude such evidence as irrelevant, unfairly prejudicial, and improper character evidence.

II. REASONABLE ROYALTY DOES NOT REQUIRE IDENTIFYING PRIOR LITIGATION INFORMATION TO ESTABLISH

Even where, as here, discrete facts and evidence from a prior lawsuit are relevant to a later case, courts *still* preclude prejudicial evidence and argument regarding litigation history and prior litigation outcomes. *Willis Electric*, D.I. 930, at 15-17 ("Accordingly, Polygroup is precluded from presenting any evidence or argument regarding the prior lawsuits, *even if Willis Electric references intellectual property issues*, under Federal Rules of Evidence 402, 403 and 404(b).").

#: 13254

In this case, both parties referenced certain contained facts from the prior litigation pertaining solely to damages in their damages expert reports. Invitae, understanding these facts are amenable to reduction of identifying information without diminishing their probative value, proposed exactly that solution when meeting and conferring with Natera regarding prospective motions *in limine*. Natera, however, refused, thus necessitating this motion.

Notably, Natera's refusal was not predicated upon any faults in Invitae's suggested solution, but merely upon the misguided notion that Invitae's prior litigation history and the outcome of the prior litigation is relevant. As documented above, however, the law is squarely to the contrary.

For these reasons, Invitae respectfully requests the Court preclude evidence and argument from Natera regarding the prior litigation, aside from the discrete damages evidence raised in both parties' damages expert reports, and preclude evidence and argument regarding said damages evidence intended to prejudicially leverage the outcome of the prior litigation.

Dated: February 9, 2024

Respectfully submitted,

FARNAN LLP

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Attorneys for Plaintiff Laboratory Corporation of America Holdings

CERTIFICATE OF SERVICE

I, Brian E. Farnan, hereby certify that on February 9, 2024, a copy of PLAINTIFF INVITAE CORPORATION'S MOTION IN LIMINE NO. 2: TO EXCLUDE EVIDENCE AND ARGUMENT REGARDING THE PRIOR LITIGATION BETWEEN INVITAE AND NATERA was served on the following as indicated:

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Attorneys for Defendant Natera, Inc.

/s/ Brian E. Farnan
Brian E. Farnan

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

C.A. No. 21-cv-669-GBW

C.A. No. 21-cv-1635-GBW

NATERA'S OPPOSITION TO LABCORP'S MOTION IN LIMINE NO. 2

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Exhibit 19

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Labcorp seeks to exclude argument and evidence regarding *Natera, Inc. v. ArcherDX, Inc. et al.*, No. 20-125 (D. Del.) (the "*ArcherDX* Case"), but that case is relevant to multiple issues in this case, including obviousness and damages. A blanket prohibition on all references to the *ArcherDX* Case is unwarranted and belied by Labcorp's own conduct. Labcorp concedes that evidence from the *ArcherDX* Case is relevant to its claims for damages. And Labcorp moved this Court for production of materials from the *ArcherDX* Case, and as part of this Pretrial Order, is submitting deposition designations from the *ArcherDX* Case (to which Natera has objected).

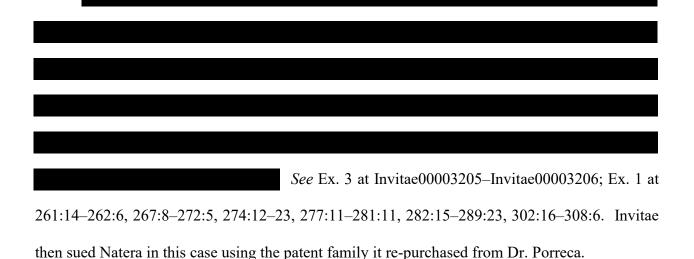
I. THE RELEVANT FACTS

How Invitae ended up owning the Asserted Patents, and the timing of it, is directly relevant to the hypothetical negotiation and whether the patented invention is commercially successful. Neither Labcorp nor Invitae invented what is claimed by the Asserted Patents. At the time that Dr. Gregory Porreca conceived of the claimed invention, he led Good Start Genetics, which he had founded.

Ex. 2 at 283:18–21, 284:15–285:19, 301:25–304:6. There is no

The '799 Patent issued on March 31, 2020, which is the date of the hypothetical negotiation in this case. In October 2020, Invitae acquired ArcherDX, a competitor to Natera. At that time, ArcherDX was a defendant in a lawsuit brought by Natera, the *ArcherDX* Case.

dispute that evidence of these transactions is relevant and admissible.



II. ARGUMENT

Labcorp agrees that the history by which, and the prices at which, Invitae purchased, sold, then re-purchased the Asserted Patent family is relevant in this case. But that history is incomplete without evidence of the circumstances in which Invitae purchased the Asserted Patent family in 2021. The **complete** transaction history is relevant to at least two disputed issues in this case.

Damages: As the parties agree, the hypothetical negotiation here is between Natera and Molecular Loop, not Invitae (or Labcorp). Natera's damages expert argues that the price at which Molecular Loop sold the Asserted Patent family in 2021 bears on the reasonable royalty. Labcorp's expert counters that the price was "significant[ly] discount[ed]" relative to the price of a hypothetical negotiation. Ex. 4 at 61. But the evidence shows that the reason Invitae bought the Asserted Patents at an allegedly "discounted" price was to sue Natera. The jury should be permitted to take this into account when determining whether the 2021 agreement is comparable.

Secondary Considerations: Labcorp argues that the commercial success of products embodying the Asserted Claims, as well as industry recognition and long-felt, unmet need, support the nonobviousness of the claimed invention. *See, e.g.*, Ex. 5 at 21–25; Ex. 6 ¶¶ 1330–1335. In response, Natera should be able to put on evidence about the circumstances by which Invitae

acquired the Asserted Patents and whether and how those transactions reflect or bear on this supposed industry recognition, long-felt, unmet need, and commercial success. *See, e.g.*, *Personalized User Model, L.L.P. v. Google Inc.*, No. 09-525, 2014 WL 807736, at *3 (D. Del. Feb. 27, 2014) ("[C]ircumstances surrounding the sale of the patents is relevant to rebutting [Patent Owner's] contentions that the patents are commercially successful."). That is, the history of how and why Invitae came to own the Asserted Patents, sell them, and buy them back is relevant to its claims that the patents are non-obvious. *Id.* It would be prejudicial to Natera for Labcorp to present arguments regarding secondary considerations without permitting Natera to respond with evidence of how Invitae viewed the Asserted Patents.

Labcorp's cases are inapposite. Natera does not seek to use evidence from the *ArcherDX* Case for an improper purpose, i.e., as substantive evidence, *see Johns Hopkins Univ. v. Alcon Lab'ys. Inc.*, No. 15-525, 2018 WL 4178159, at *21 (D. Del. Aug 30, 2018), or to attack Invitae's character, *see Willis Elec. Co., Ltd. v. Polygroup Ltd. et al.*, No. 15-3443, D.I. 930, at 15–16 (D. Minn Jan. 5, 2024); *see also 10X Genomics, Inc. v. Nanostring Techs., Inc.*, No. 21-653, D.I. 277, at 3 (D. Del. Nov. 2, 2023) (precluding evidence of willful infringement in prior litigation); *AVM Techs. LLC v. Intel Corp.*, No. 15-33, D.I. 637, at 1–2 (D. Del. Apr. 19, 2017) (precluding evidence of summary judgment of no damages in prior litigation); *CellTrust Corp. v. Ionlake, LLC*, No. 1-2855, 2023 WL 3052733, at *4–6 (D. Minn. Apr. 23, 2023) (precluding evidence of other lawsuits); *Cosmos Granite (W.), LLC v. Minagrex Corp.*, No. 19-1697, 2021 WL 5140226, at *2 (W.D. Wash. Nov. 4, 2021) (same).

To be sure, there may be aspects of the *ArcherDX* Case that are inadmissible, as Natera explains in its second motion *in limine*. But a blanket ban on any mention it, or of how and why Invitae acquired the Asserted Patents would prejudice Natera. Labcorp's motion should be denied.

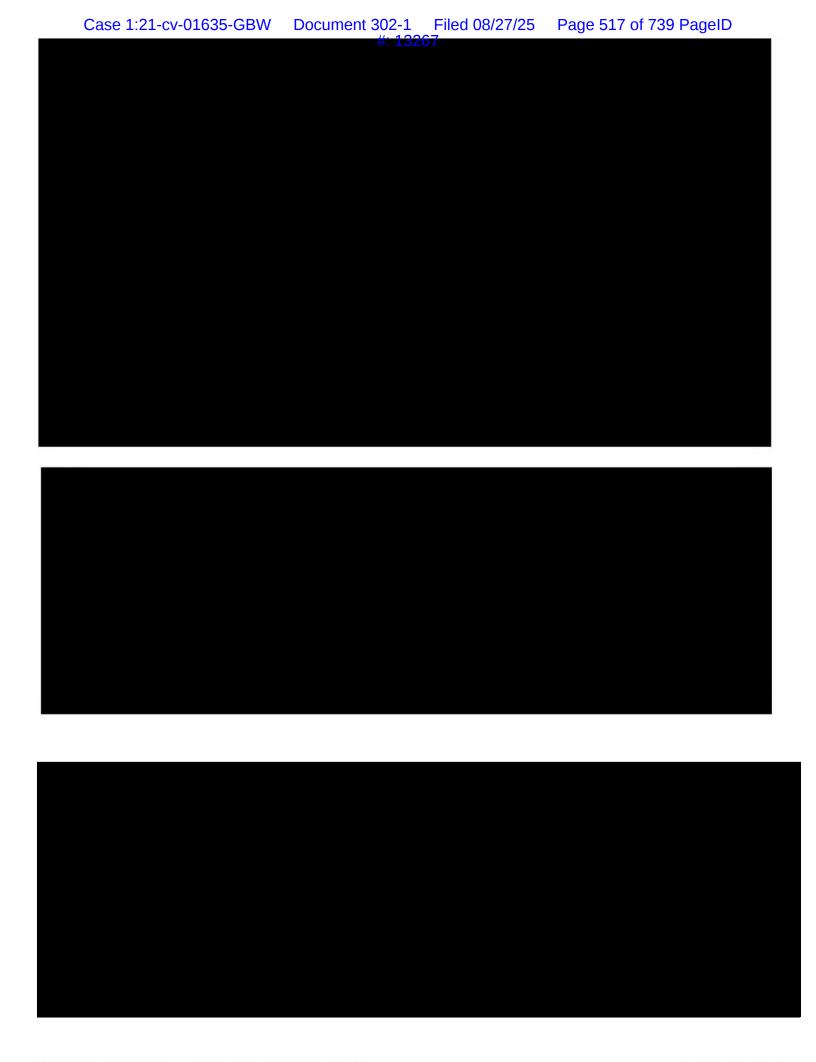
EXHIBIT 1

REDACTED

EXHIBIT 2

REDACTED

EXHIBIT 3



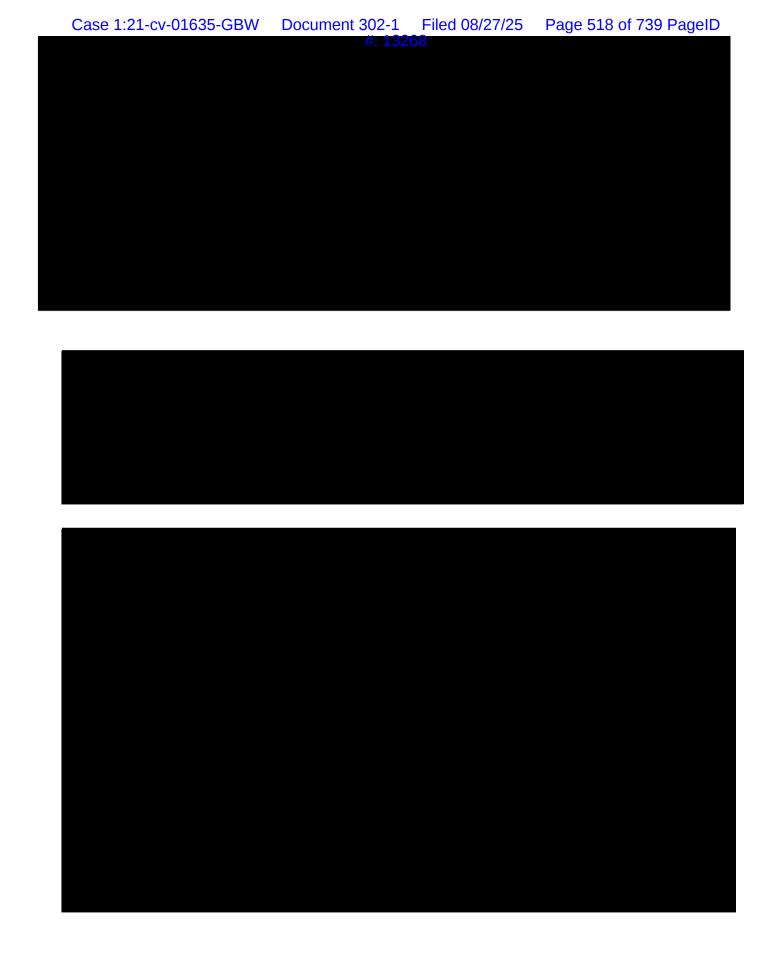


EXHIBIT 4



INVITAE CORPORATION

V.

NATERA, INC.

Civil Action Nos. 1:21-cv-00669 & 1:21-cv-01635

United States District Court for the District of Delaware

EXPERT REPORT OF ALEXANDER L. CLEMONS

June 16, 2023

INTELLECTUAL CAPITAL EQUITY

established the marketplace."312 Similarly, even in June 2021, DeciBio explained that, "[o]verall, the MRD / monitoring space is still in the relatively early stages of research, development, and clinical adoption today."313 As of October 2018, Signatera had launched for research use only, but would not launch commercially for clinical use for almost another year.³¹⁴ Additionally, Signatera's rapid revenue growth from 2019 through 2022 would not be known in 2018.315 The lump sum purchase price for the MIP Assets, originally set in the July 2017 Merger Agreement, does not account for these and other developments in the MRD market. However, a running royalty, such as the 10% royalty rate contained in the BD / ArcherDX License, by its very nature, results in increased or decreased royalty payments as licensed sales increase or decrease.

Fourth, even if the financial terms of the Good Start / Molecular Loop Asset Purchase and Royalty Agreements could be argued to include value relating to the use of the Patents-in-Suit by third parties, such as Natera, any such value would include a significant discount to account for the costs and risks associated with attempting to license or litigate with such third party, such as the cost of a licensing program, the cost of patent litigation, the risk of patents being found invalid, and the risk of patents being found non-infringed. In the context of the hypothetical negotiation, however, the Patents-in-Suit are assumed to be valid and infringed.

Based on the above, the Good Start / Molecular Loop Asset Purchase and Royalty Agreements are not economically comparable to a license that would result from the hypothetical negotiation in this case and are not indicative of the value of the Patents-in-Suit or a reasonable royalty for the Patents-in-Suit.

Molecular Loop / Invitae Asset Purchase and Cross License Agreements

Effective March 13, 2021, Invitae and Molecular Loop entered into an "Asset Purchase Agreement." 316 Effective the same day, Invitae and Molecular Loop entered into a "Cross License Agreement" (the Asset Purchase Agreement and the Cross License Agreement referred to as the "Molecular Loop / Invitae Asset

³¹² Deposition of Kevin Masukawa, February 28, 2023, pp. 63, 84.

³¹³ Zhou, Susan, "Industry Snapshot: The nascent ctDNA MRD space continues to see rapid growth," DeciBio, June 29, 2021, https://www.decibio.com/insights/industry-snapshot-the-nascent-ctdna-mrd-space-continues-to-see-rapidgrowth.

^{314 &}quot;Natera Launches SignateraTM Personalized Circulating Tumor DNA Technology for Cancer Research," Natera, August 21, 2017, https://www.prnewswire.com/news-releases/natera-launches-signatera-personalized-circulatingtumor-dna-technology-for-cancer-research-300506771.html; Natera, Inc., SEC Form 10-K for the fiscal year ended December 31, 2019, p. 15, https://d18rn0p25nwr6d.cloudfront.net/CIK-0001604821/fb612ec5-278c-4e4c-bfbafa516dd7f4d8.pdf.

³¹⁵ Appendix 7.1; INVT-00419829, tab "Signatera Gross Profit".

³¹⁶ Invitae0000003173-188 at 173-174.

royalties, in addition to or as an alternative to lost profits, I have analyzed quantitative and qualitative valuation metrics, including the *Georgia-Pacific* factors, and have reached a conclusion regarding the appropriate reasonable royalties due to Invitae for Natera's use of the Patents-in-Suit in connection with the Accused Product. As summarized in the figure below, I have calculated total damages, both including and excluding lost profits.

Figure 26: Summary of Damages through 2022⁵¹¹

I reserve the right to update my damages calculations if updated sales information is provided.

16 SIGNATURE

Respectfully submitted,

Alexander L. Clemons

June 16, 2023

Date

511 Appendix 3.1.

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

INVITAE CORPORATION,)
Plaintiff,) Case No. 21-cv-669-GBW
v.	JURY TRIAL DEMANDED
NATERA, INC.)
Defendant.)))
INVITAE CORPORATION,) Case No. 21-cv-01635-GBW
Plaintiff,	JURY TRIAL DEMANDED
v.)
NATERA, INC.)
Defendant.))
	/

INVITAE CORPORATION'S SUPPLEMENTAL RESPONSES AND OBJECTIONS TO NATERA, INC.'S FIRST SET OF INTERROGATORIES (NOS. 1-8)

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, the Local Rules of the United States District Court for the District of Delaware ("Local Rules"), the District of Delaware Default Standard for Discovery, including Discovery of Electronically Stored Information ("Default Standard"), and any other applicable Orders or rules, Plaintiff Invitae Corporation ("Invitae") hereby makes the following supplemental responses and objections to Defendant Natera, Inc.'s ("Natera") First Set Of Interrogatories (Nos. 1-8).

assembly that allows accurate identification of certain cancer-causing mutations that are otherwise difficult to identify.

The nonobviousness of the Asserted Patents is further shown by industry praise for the Genome Analysis Toolkit (GATK) tools identified as used in the Accused Products upon information and belief. *See generally* D.I. 1. For example, the Mutect2 tool in GATK is described as "stable and relatively accurate" and "one of the most widely used mutation-calling tools". *See* Chen, Z., Yuan, Y., Chen, X. et al., *Systematic comparison of somatic variant calling performance among different sequencing depth and mutation frequency*. Sci Rep 10, 3501 (2020).

As required under the scheduling order and the local rules, Invitae will provide expert testimony regarding the nonobviousness of the Asserted Patents.

FIRST SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 2 (2023-02-15):

Subject to its general and specific objections, and based on its investigation to date, Invitae supplements its response to further respond as follows:

Facts further supporting objective indicia of non-obviousness of Invitae's Asserted Patents include the commercial success attributable to the claimed inventions in the products that embody and/or infringe the Asserted Patents. Such facts include without limitation: the high level of commercial success of Invitae's embodying products and Natera's accused Signatera products attributable to the claimed inventions; the speed with which Invitae's embodying products and Natera's accused Signatera products achieved commercial success; the significant sales and revenues of Invitae's embodying products and Natera's accused Signatera products attributable to the claimed inventions; the large number of clinicians, patients, pharma partners, academia partners, and other collaborators adopting Invitae's embodying products and Natera's accused Signatera products attributable to the claimed inventions; the large number and wide extent of

Natera's collaboration and partnerships with pharmaceutical companies, academia, federal health care system members, BGI, FMI, and others involving the accused Signatera products attributable to the claimed inventions; the number of publications utilizing and/or discussing Invitae's embodying products and Natera's accused Signatera products attributable to the claimed inventions; the market shares of Invitae's embodying products and Natera's accused Signatera products attributable to the claimed inventions; the regulatory status of the accused Signatera products (e.g., FDA approval and CE marking) attributable to the claimed inventions; the coverage of the accused Signatera products from private or public insurance companies/agencies (e.g., Medicare and Medicare Advantage) attributable to the claimed inventions; and third-party reports discussing the above. Such commercial success also supports that there existed a long-felt, unmet need in the industry and that prior attempts to meet that need failed.

Facts further supporting objective indicia of non-obviousness of Invitae's Asserted Patents also include the industry praise and recognition for the inventions of the Asserted Patents, for software and bioinformatics tools that perform key steps of Invitae's Asserted Patents, and for the products that embody or infringe Invitae's Asserted Patents attributable to the claimed inventions. Such facts include without limitation: awards won by Invitae's embodying products and Natera's accused Signatera products attributable to the claimed inventions; awards won by Sentieon's software attributable to the implementation of GATK HaplotypeCaller and Mutect 2 (e.g., https://www.sentieon.com/products/, https://precision.fda.gov/challenges/truth/results, https://precision.fda.gov/challenges/10/results); awards won by, industry recognition of, and wide adoption of Broad Institute GATK attributable to the claimed inventions (e.g., https://www.nature.com/articles/srep17875,

https://www.sciencedirect.com/science/article/pii/S2001037019301473,

https://csc.fi/ja/web/blog/post?p p id=com liferay blogs web portlet BlogsPortlet&p p lifecy cle=0&p p state=normal&p p mode=view&p r p categoryId=394145); professional acclaim for Invitae's embodying products and Natera's accused Signatera products attributable to the claimed inventions (e.g., research papers discussing or utilizing and clinical studies utilizing Invitae's embodying products and Natera's accused Signatera products); industry reports discussing and praising the success or advantages of Invitae's embodying products and Natera's accused Signatera products attributable to the claimed inventions; competitors discussing, comparing and praising the success or advantages of Invitae's embodying products and Natera's accused Signatera products attributable to the claimed inventions; the large number of clinicians, patients, pharma partners, academia partners, and other collaborators adopting Invitae's embodying products and Natera's accused Signatera products attributable to the claimed inventions; the large number and wide extent of Natera's collaboration and partnerships with pharmaceutical companies, academia, federal health care system members, BGI, FMI, SRL, and others involving the accused Signatera products attributable to the claimed inventions; the number of publications utilizing and/or discussing Invitae's embodying products and Natera's accused Signatera products attributable to the claimed inventions; the regulatory status of the accused Signatera products (e.g., FDA approval and CE marking) attributable to the claimed inventions; the coverage of the accused Signatera products from private or public insurance companies/agencies (e.g., Medicare and Medicare Advantage) attributable to the claimed inventions; and third party reports discussing and praising Invitae's embodying products and Natera's accused Signatera products attributable to the claimed inventions. The industry praise and recognition attributable to the claimed inventions also support that the industry recognized the significance and unexpected results of the inventions of Invitae's Asserted Patents and products that embody or infringe Invitae's Asserted Patents.

Facts further supporting objective indicia of non-obviousness of Invitae's Asserted Patents also include the existence of long-felt, persistent need in the industry recognized by skilled artisans that had not been satisfied before the inventions of the Asserted Patents but was satisfied by the inventions of the Asserted Patents. Such facts include without limitation: the Asserted Patents and the prosecution histories discussing the drawbacks, failings, and needs not met by prior art; the Asserted Patents and the prosecution histories discussing the benefits of the inventions of the Asserted Patents and how the inventions meet needs not met by prior art; publications discussing the drawbacks, failings, and needs not met by prior art; publications discussing the benefits of the inventions of the Asserted Patents and how the inventions meet needs not met by prior art; discussion of differences between the inventions in the Asserted Patents and prior art; discussions of the benefits of Invitae's embodying products and Natera's accused Signatera products attributable to the claimed inventions, discussions of the differences between Invitae's embodying products and Natera's accused Signatera products attributable to the claimed inventions and prior art products and techniques, and of how Invitae's embodying products and Natera's accused Signatera products meet needs not met by prior art products and techniques attributable to the claimed inventions; industry reports discussing the drawbacks, failings, and needs not met by prior art products and techniques, the benefits of Invitae's embodying products and Natera's accused Signatera products attributable to the claimed inventions, the differences between Invitae's embodying products and Natera's accused Signatera products attributable to the claimed inventions and prior art products and techniques, and how Invitae's embodying products and Natera's accused Signatera products meet needs not met by prior art products and techniques

attributable to the claimed inventions; documents produced by the parties discussing the aforementioned exemplary facts.

Facts further supporting objective indicia of non-obviousness of Invitae's Asserted Patents also include the presumption of the existence of and/or the existence of a nexus between the objective considerations described above and the claimed inventions in Invitae's Asserted Patents. Such facts include without limitation: Natera's accused Signatera products infringe claims of Invitae's Asserted Patents; Invitae's embodying products embody claims of Invitae's Asserted Patents; the secondary considerations described above attributable to the fact that Invitae's embodying products and/or Natera's accused Signatera products practice Invitae's Asserted Patents; the secondary considerations described above did not solely result from factors other than the claimed inventions; and documents from the parties and from third parties recognizing, discussing, or otherwise confirming the above. For example, Invitae's embodying products and Natera's accused Signatera products use modified versions of GATK HaplotypeCaller and/or Mutect 2 to perform sequence assembly and alignment and variant calling using genetic sequence The sequencing, sequence analysis, and variant calling processes are integral to the data. functionality of these products. These products are personalized cancer recurrence monitoring products that require identification of somatic mutations unique to each patient. establishing the patient-unique variant profile, which is obtained using the claimed invention, Invitae's embodying products and Natera's accused Signatera products do not function as claimed. Thus, the claimed inventions are key to the functionality of both genetic testing products. While Invitae's embodying product uses an in-house modification of GATK and Natera's Signatera uses Sentieon's implementation of GATK, the underlying operation is not changed and practices the claimed invention of the Asserted Patents. Further, the claimed inventions, including the two

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

INVITAE CORPORATION,

Plaintiff,

v.

NATERA, INC.

Defendant.

INVITAE CORPORATION,

Plaintiff,

v.

NATERA, INC.

Defendant.

Case No. 21-cv-669-GBW

JURY TRIAL DEMANDED

HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY

Case No. 21-cv-1635-GBW

JURY TRIAL DEMANDED

HIGHLY CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY

REBUTTAL EXPERT REPORT OF DAN E. KRANE TO THE OPENING EXPERT REPORT OF MICHAEL METZKER, PHD

Dated: July 21, 2023

Dr. Dan E. Krane

By: Dan E. Rame

x. Claim 27: "the sequence reads comprise at least one million sequence reads"

- 1328. Dr. Metzker opines that Li (2009) anticipates and/or renders obvious '308 Claim 27 for the reasons described for '308 Claim 19. Metzker Opening Report ¶ 1730. I disagree and incorporate my analysis of '308 Claim 19 by reference. *See supra* analysis for '308 Claim 19.
- 1329. Li (2009) does not anticipate or render obvious this claim also because it does not anticipate or render obvious Claim 20. *See supra* analysis for '308 Claim 20.

L. Objective Indica of Non-Obviousness

- 1330. In addition to my analyses *supra*, I also provide an analysis in this section regarding objective indicia of nonobviousness. In addition to other documents I cite below, I reference the Asserted Patents and their file histories throughout. *See* Invitae000000001, Invitae0000002509, Invitae0000002795.
- Assertd Patents that is attributable to the claimed inventions supports objective indicia of non-obviousness. For example, Invitae's embodying products and Natera's accused Signatera products are both commercially successful, became commercially successful quickly, and made significant sales and revenues, with a substantial market share. For example, Natera's Form 10-K submitted on February 25, 2022, on page 37, describes the high level of competition in the market space. Additionally, a large number of clinicians, patients, pharma partners, academia partners, and other collaborators adopted these same products, such as but not limited to Natera's collaborations and partnerships with BGI, FMI, and others, or the scientific publications which utilize and/or discuss the aforementioned products. See, e.g., Invitae0010003276 (describing among other things the quality and capability of Invitae's embodying products for use in academic studies); NTRA-INVT-00016144 at 16159, 16163 (Natera's BD Pharma Core Deck). Additionally, the regulatory

status (such as FDA approval and CE marking) and coverage from public and private insurance (such as Medicare and Medicare Advantage) of the accused Signatera products also supports this. All of these commercial successes as described also support the long-felt and unmet need in the industry for the claimed inventions described *infra*.

1332. Second, there was also a long-felt and unmet need in the industry for the claimed inventions, and prior attempts to meet that need failed. Specifically, the long-felt but unresolved needs in the industry for a sequence assembly tool capable of overcoming the limitations of then-current software, which required researchers to compromise between sensitivity to different types of mutations. Even more so, prior software required tradeoffs between positional accuracy, being able to include detailed information from each read, and difficulty interpreting certain types of mutations altogether, as are all documented in the prior art Dr. Metzker has provided. The long-felt need for a solution to these problems that could be implemented in connection with existing platforms, which the claimed methods provide, shows nonobviousness. As explained *supra* the facts demonstrating commercial success also support the existence of a long-felt and unmet need in the industry for the claimed inventions.

1333. Third, the nonobviousness of the Asserted Patents is further shown by industry praise and recognition attributable to the claimed inventions for the inventions of the Asserted Patents, for software and bioinformatics tools that perform key steps of Invitae's Asserted Patents, and for the products that embody of infringe Invitae's Asserted Patents. For example, Sentieon's software has won a number of awards attributable to their implementation of GATK HaplotypeCaller and Mutect2. Exs. 3, 4, and 5. As another example, the variant calling tool in GATK is described as "stable and relatively accurate" and "one of the most widely used mutation-

calling tools." Ex. 6; see also, e.g. ILLUMINA-0008343 (explaining that GATK is industry standard); Invitae0010017712 (explaining that GATK is the default);

Patents. For a variant caller, factors for its success include the speed and accuracy of the sequence analysis and variant calling processes. My understanding is substantiated by my experience as I describe *supra* as well as, at least, testimony from Eric Banks regarding his experience developing HaplotypeCaller. *See* Banks Depo. at 166:1-168:9. Additionally, GATK is the industry standard, and is the most widely adopted caller in bioinformatics. *See* NTRA-INVT-00234865 at 234867 ("Put together the pipeline using Sentieon Haploptyper, an improved version of the *industry standard GATK Haplotype Caller* for short variant SNV/INDEL calling and post processing steps of decomposing multiple allelic calling..."). Additionally, Dr. Raheleh Salari testified that

The Cancer Genome

Atlast (TCGA) had already validated GATK. See Salari Depo at 68:9-69:4; 69:23-70:14. This is in accord with my understanding of the field. The embodying and accused products are personalized cancer recurrence monitoring products that require the precise identification of mutations unique to each patient. Without identifying such mutations, Invitae's embodying products and Natera's accused Signatera products do not function as described. Thus, the claimed invention is necessary for the proper function of both products. See Krane Opening Report Part XI; NTRA-INVT-00016144 at 16162. I incorporate by reference my opinions regarding the variant calling process in Signatera in my opening report. As Invitae's embodying products use an in-house modification of GATK and Natera's Signatera uses a licensed Sentieon implementation of GATK, it can be seen that the underlying sequence assembly and analysis functions, which practice the claimed invention of the Asserted Patents, are the key features of

from the Asserted Patents that are both desireable and unchanged between the products. Additionally, the claimed invention, including the novel and inventive two-step alignment enable variant callers such as GATK HaplotypeCaller and Mutect2 to call variants (including SNVs and indels) with greater accuracy and less computational resources than other variant callers which do not practice the claimed invention, such as GATK UnifiedGenotyper.

1335. For at least these reasons, it is my understanding that the objective indicia of nonobviousness show that the Asserted Claims are not obvious.

XI. SECTION 112 ANALYSIS

1336. I disagree with Dr. Metzker's Section 112 analysis.

A. Validity Based Upon Enablement and Written Description

1337. I have been informed that Section 112 of the Patent Code requires the specification of a patent to enable one of ordinary skill in the art to practice the full scope of the claimed invention without undue experimentation as of the filing date of the patent. I have also been informed that the specification, drawings, and claims in a patent must allow a person of ordinary skill in the art to recognize that the invention was invented by the patentee and was in the patentee's possession at the time of filing. I understand these requirements.

1338. I have been asked to analyze whether the Asserted Patents satisfy the written description and enablement requirements and to thusly respond to Dr. Metzker's opinions. It is my opinion that Dr. Metzker is incorrect in his analyses and that the Asserted Patents are adequately described and sufficiently enabled for one of ordinary skill in the art at the time of Asserted Patents' filings.

1339. Dr. Metzker's opinion is premised on the wrong understanding of the term "mutations"—" the claimed 'mutations' detectable by methods of the invention, is interpreted to

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY AMERICA HOLI	CORPORATION OF DINGS,)	
	Plaintiff,)	C.A. No. 21-669 (GBW)
v.)	
NATERA, INC.)	
	Defendant.		
LABORATORY AMERICA HOLI	CORPORATION OF DINGS,)	
	Plaintiff,))	C.A. No. 21-1635 (GBW)
v.)	
NATERA, INC.)	
	Defendant.)	

PLAINTIFF'S REPLY IN SUPPORT OF ITS MOTION IN LIMINE NO. 2: TO EXCLUDE EVIDENCE AND ARGUMENT REGARDING THE PRIOR LITIGATION BETWEEN INVITAE AND NATERA

OF COUNSEL:

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Dated: August 13, 2025

Brian E. Farnan (Bar No. 4089) Michael J. Farnan (Bar No. 5165) FARNAN LLP 919 North Market St., 12th Floor Wilmington, DE 19801 Tel: (302) 777-0300 Fax: (302) 777-0301 bfarnan@farnanlaw.com mfarnan@farnanlaw.com

Attorneys for Plaintiff Laboratory Corporation of America Holdings Natera confirms that it intends to discuss *ArcherDX* to argue before the jury that "Invitae bought the Asserted Patents...to sue Natera." Opp. at 2. Natera thus intends to improperly pursue a narrative that Invitae purchased the Asserted Patents as revenge for first being sued by Natera.

Whether Invitae purchased the Asserted Patents solely to assert against Natera is disputed.¹ Even if true, however, there is nothing nefarious about this. Moreover, this has no relevance to whether Natera infringed the Asserted Patents, the Asserted Patents' validity, or the related damages. The only purpose Natera's argument serves is to paint Labcorp in a bad light. Yet, as Natera itself argued in the prior *ArcherDX* case, "[a]llowing Defendant[] to present nonsensical arguments irrelevant to the issues before the jury would not only waste time but also divert the jury's attention to extraneous matters." No. 20-cv-125, D.I. 580-1, Ex. 17-3 at 2.

As to damages, Natera contends that the jury needs to know Invitae's motivation to purchase the Asserted Patents—purportedly retaliation for Natera's prior lawsuit—to evaluate the purchase agreement for the hypothetical negotiation. Neither party's damages experts, however, presents valuations dependent on Invitae's motivation for filing suit. As to secondary considerations, Natera contends that "the history of how and why Invitae came to own the Asserted Patents, sell them, and buy them back is relevant to its claims that the patents are non-obvious." Opp. at 3. As the *Google* case cited by Natera explains, however, what is relevant to commercial success is "[e]vidence of [*the patentee*]'s financial state prior to selling the patents-in-suit." 2014 WL 807736, at *3. The relevant circumstances are those of Molecular Loop, who sold the patent, not of Invitae. Natera cites no case allowing the inflammatory contention that a party purchased a patent for retaliatory litigation to be used for damages or secondary considerations.

¹ Ex. 1 at 311:4-8

August 13, 2025

Respectfully submitted,

FARNAN LLP

/s/ Brian E. Farnan

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Attorneys for Plaintiff Laboratory Corporation of America Holdings

CERTIFICATE OF SERVICE

I, Brian E. Farnan, hereby certify that on August 13, 2025, a copy of PLAINTIFF'S REPLY IN SUPPORT OF ITS MOTION IN LIMINE NO. 2: TO EXCLUDE EVIDENCE AND ARGUMENT REGARDING THE PRIOR LITIGATION BETWEEN INVITAE AND NATERA was served on the following as indicated:

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/s/ Brian E. Farnan

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EXHIBIT 1

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 542 of 739 PageID

REDACTED

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 543 of 739 PageID

EXHIBIT 19C

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

AMERICA HOLDI)
	Plaintiff,) C.A. No. 21-669 (GBW)
v.)
NATERA, INC.)
	Defendant.	ý ,
LABORATORY CO AMERICA HOLDI		
	Plaintiff,) C.A. No. 21-1635 (GBW)
v.)
NATERA, INC.)
	Defendant.)

PLAINTIFF'S MOTION IN LIMINE NO. 3: TO EXCLUDE EVIDENCE AND ARGUMENT REGARDING INVITAE'S OVERALL FINANCIAL CONDITIONS

OF COUNSEL:

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Dated: February 9, 2024

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Attorneys for Plaintiff Laboratory Corporation of America Holdings Pursuant to Federal Rules of Evidence 402 and 403, Plaintiff Invitae Corporation ("Invitae") moves to preclude Defendant Natera, Inc. ("Natera") from offering evidence, testimony, argument, or otherwise referencing Invitae's overall financial condition, including potential bankruptcy, delisting from NYSE, stock price, and employee layoffs, etc. Invitae's overall financial condition now, or in the past, is wholly irrelevant to Invitae's claim for patent infringement. But even if it has some marginal relevance here, its probative value is substantially outweighed by that it would unfairly prejudice Invitae and confuse or mislead the jury.

I. INVITAE'S OVERALL FINANCIAL CONDITION IS IRRELEVANT TO ANY ISSUE IN THIS CASE.

A party's overall financial condition has no relevance to any issue relating to infringement or patent validity. *See, e.g., Collier v. Airtex, Inc.*, No. 87 C 4097, 1990 WL 119551, at *1 (N.D. Ill. Aug. 14, 1990) ("Evidence of plaintiffs' financial condition does not appear to be relevant to any issue relating to infringement or patent validity."); *Liqwd, Inc. v. L'Oreal USA, Inc.*, C.A. No. 17-14-JFB-SRF, 2019 WL 2775515, at *1 (D. Del. July 2, 2019) ("The Court agrees that any evidence as to defendants' overall financial status is irrelevant and is potentially prejudicial."). There is no reason this case should be an exception to this commonsense principle.

At the parties' meet and confer, Natera contended that evidence regarding Invitae's overall financial condition is relevant to lost profits, reasonable royalty, and future damages. Natera's position lacks merit. Indeed, neither sides' experts discussed Invitae's overall financial condition in forming their opinions on damages.

Lost profits. Invitae's overall financial condition is not relevant to lost profits analysis, including the third *Panduit* factor—"manufacturing and marketing capability." *Panduit Corp. v. Stahlin Bros. Fibre Works*, 575 F.2d 1152, 1156 (6th Cir. 1978). Invitae's overall financial condition is distinct from its manufacturing and marketing capacity of its PCM product (the lost

sales of which caused Invitae's lost profits). Invitae as a company has numerous product lines. And its financial performance is determined by many factors beyond its product sales. Either Invitae has the capacity to fill the market relevant for lost profits, or it does not. There is no need for Natera to raise allegations about employee layoffs or bankruptcy status.

Reasonable royalty. Invitae's overall financial condition is not relevant to reasonable royalty either. To determine a reasonable royalty, a hypothetical negotiation would have taken place at the time of first infringement between the patent owner and the infringer. *See Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009). In this case, the hypothetical negotiation would have taken place on March 31, 2020 (issuance date of the '799 Patent) between third-party Molecular Loop (then patent owner) and Natera. Hence, the reasonable royalty analysis requires no inquiry into Invitae's overall financial condition, especially its recent condition.

<u>Future damages</u>. Future damages is typically resolved by post-trial briefing. Thus, to the extent Invitae's financial condition is relevant to future damages, it should be addressed *after* the jury returns a verdict.

II. EVIDENCE OF INVITAE'S OVERALL FINANCIAL CONDITION IS HIGHLY PREJUDICIAL TO INVITAE AND WILL CONFUSE OR MISLEAD THE JURY

Allowing Natera to present evidence regarding Invitae's overall financial condition to the jury would be highly prejudicial to Invitae because such evidence has no purpose except to paint Invitae in a bad light. Such evidence is intended only to confuse or mislead the jury from the key issues in the case, which are whether Natera infringes Invitae's patents. *See, e.g., In re Homestore.com, Inc. Sec. Litig.*, No. CV 01-11115 RSWL (CWx), 2011 WL 291176, at *1 (C.D. Cal. Jan. 25, 2011) ("Evidence of a party's financial condition is generally not relevant and can be unduly prejudicial, as it can distract the jury from the real issues in the case.").

Evidence regarding bankruptcy is particularly likely to taint the jury's opinion of a party, thereby resulting in unfair prejudice and confusion. *See, e.g., HTC Corp. v. Tech. Properties Ltd.*, No. 5:08-CV-00882-PSG, 2013 WL 4782598, at *2 (N.D. Cal. Sept. 6, 2013) ("A reference to bankruptcy may trigger visceral reactions among jurors and the court believes such a reaction carries a risk of substantial unfair prejudice. Moreover, there is a substantial risk that evidence of TPL's bankruptcy will confuse the issues."); *HSM Portfolio LLC v. Elpida Memory Inc.*, C.A. No. 11-770-RGA, D.I. 1220 at 2 (D. Del. Feb. 17, 2016) ("TPL's bankruptcy is excluded, since being bankrupt does not make a company more avaricious than if it is not bankrupt. It is also unfairly prejudicial, and thus even were there some slight probative value, it would be greatly outweighed by the prejudice."); *Magelky v. BNSF Ry. Co.*, No. 1:06-CV-025, 2008 WL 238451, at *2 (D.N.D. Jan. 28, 2008) ("[Evidence of bankruptcy], even if relevant, would be unfairly prejudicial, confuse the issues, mislead the jury, and result in undue delay and a waste of time. Therefore, such evidence shall be excluded pursuant to Rule 403 of the Federal Rules of Evidence").

Given its lack of probative value and the high likelihood of jury confusion and unfair prejudice to Invitae, Defendant should be precluded from introducing evidence or argument concerning Invitae's overall financial condition.

Dated: February 9, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Brian E. Farnan, hereby certify that on February 9, 2024, a copy of PLAINTIFF INVITAE CORPORATION'S MOTION IN LIMINE NO. 3: TO EXCLUDE EVIDENCE AND ARGUMENT REGARDING INVITAE'S OVERALL FINANCIAL CONDITIONS was served on the following as indicated:

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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION OF
AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

C.A. No. 21-cv-669-GBW

C.A. No. 21-cv-1635-GBW

NATERA'S OPPOSITION TO LABCORP'S MOTION IN LIMINE NO. 3

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Exhibit 19

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Invitae's business began collapsing in mid-2022, and Invitae filed for Chapter 11 bankruptcy on February 13, 2024. Plaintiff Labcorp then bought substantially all of Invitae's assets in that bankruptcy, including these Asserted Patents and the part of Invitae's business that competed with Natera's accused product, Signatera. Labcorp now seeks to preclude Natera from referencing or offering evidence or argument regarding what the moving brief described as "Invitae's overall financial condition, including potential bankruptcy, delisting from NYSE, stock price, and employee layoffs, etc.," which Natera treats as including the subsequent bankruptcy itself. Invitae's Motion *in Limine* No. 3 ("MIL 3") at 1.

Invitae's financial condition is directly relevant to the parties' claims and defenses in this litigation, including Labcorp's claim for lost profits and its argument that secondary considerations, like commercial success, demonstrate the non-obviousness of the Asserted Patents. There are aspects of this request with which Natera agrees, but those should be taken up individually, not with a blanket ban on any mention of Invitae's financial condition.

I. ARGUMENT

Labcorp seeks Invitae's lost profits through November 2023 (i.e., before the Court's injunction of Invitae's PCM in the *ArcherDX* case), and its damages expert has opined that if Natera had not sold its accused Signatera product, "Invitae would have likely captured all (but no less than 50%) of those sales in the pharmaceutical market with sales of its PCM product." Ex. 1 at 38; *see also id.* at 4–5, 37–43, Fig. 13, 102. To recover for Invitae's lost profits, Labcorp must prove that Invitae had the manufacturing and marketing capability to make the allegedly infringing sales that were actually made by Natera. *Wechsler v. Macke Int'l Trade, Inc.*, 486 F.3d 1286, 1294

¹ *In re Invitae Corp.*, No. 24-11362-MBK, Debtors' Motion for Entry of Interim Final Orders, D.I. 18 (D.N.J. Bankr. Feb. 14, 2024); *In re Invitae Corp.*, No. 24-11362-MBK, Declaration of Ana Schrank, Chief Financial Officer of Invitae Corporation, in Support of Chapter 11 Filing, First Day Motions, and Access to Cash Collateral, D.I. 21 (D.N.J. Bankr. Feb. 14, 2024).

(Fed. Cir. 2007). Invitae's business failures are directly relevant to whether it could have in fact exploited the alleged demand for the patented product during the relevant time. *Id.* (holding lost profits not available where patentee "was unable to produce a product during the period of infringement."); *Gargoyles, Inc. v. United States*, 113 F.3d 1572, 1578 (Fed. Cir. 1997) (holding lost profits not available where patentee "has not proven capacity to produce the [additional products] sufficient to receive lost profits."); *cf., APEX Fin. Options, LLC v. Gilbertson*, No. CV 19-0046-WCB-SRF, 2022 WL 622130, at *1 (D. Del. Mar. 3, 2022) (declining to preclude evidence regarding plaintiffs' "financial condition" under Rules 402 & 403).

Evidence regarding Invitae's financial state is also relevant to the parties' arguments regarding commercial success for purposes of obviousness under 35 U.S.C. § 103. For example, Natera should be permitted to "attempt to rebut [Invitae]'s effort to show commercial success of the patents-in-suit by presenting evidence that the patents were not commercial successes for [Invitae] or [Molecular Loop Biosciences, LLC ('Molecular Loop')]," the entity from whom Invitae acquired the Asserted Patents, because "lack of commercial success may be probative evidence to rebut a showing of commercial success." Personalized User Model, L.L.P. v. Google Inc., C.A. 09-525-LPS, 2014 WL 807736, at *3 (D. Del. Feb. 27, 2014). Invitae's bankruptcy, despite it having multiple products allegedly incorporating the patented technology, is directly relevant to whether the Asserted Patents in fact led to any commercial success. Likewise, evidence showing that Invitae was "not successful at the times [it] owned the patents-in-suit is probative of [Natera]'s contention that its own commercial success is in no way due to its alleged practice of the patented technology." Id. at *3. Natera should be permitted to introduce evidence tending to show that the Asserted Patents were not a commercial success for Invitae or Molecular Loop, and that Signatera's commercial success is unrelated to the claimed invention.

Exhibit 19

There are also practical reasons why Labcorp's motion sweeps too broadly. Labcorp has been substituted for Invitae as plaintiff in this case. But nearly all the evidence given by the plaintiff party in this case is about Invitae—Invitae's sale and marketing of an allegedly competing product, Invitae's documents, Invitae's witnesses, Invitae's interactions with the inventors. And Labcorp has given no evidence about itself in this case, nor could it—discovery had long been closed by the time that Labcorp substituted in as the plaintiff. Thus, the jury will need some context for why all the evidence about the plaintiff is referring to Invitae when the named plaintiff is Labcorp, and to obscure the reason for that would be impractical for the attorneys and for the witnesses, and it would surely create juror confusion.

The cases Invitae cites in support of its broad motion *in limine* are inapposite. *See HTC Corp. v. Tech. Properties Ltd.*, No. 5:08-CV-00882-PSG, 2013 WL 4782598, at *2 (N.D. Cal. Sept. 6, 2013) (precluding mention of bankruptcy to rebut evidence on the success of plaintiff's IP licensing program); *Magelky v. BNSF Ry. Co.*, No. 1:06-CV-025, 2008 WL 238451, at *2 (D.N.D. Jan. 28, 2008) (precluding mention of plaintiff's bankruptcy in personal injury lawsuit); *HSM Portfolio LLC v. Elpida Memory Inc.*, C.A. No. 11-770-RGA, D.I. 1220 at 2–3 (D. Del. Feb. 17, 2016) (precluding use of evidence of bankruptcy as improper character evidence under Rule 404(b)). Natera does not intend to introduce evidence of Invitae's financial condition for any of these improper purposes. But Invitae has put at issue its capacity to have historically exploited the additional sales opportunities that would have existed had Natera not sold Signatera, as well as the alleged commercial success of the patented technology. That puts Invitae's financial situation at issue in this case.

EXHIBIT 1



INVITAE CORPORATION

V.

NATERA, INC.

Civil Action Nos. 1:21-cv-00669 & 1:21-cv-01635

United States District Court for the District of Delaware

EXPERT REPORT OF ALEXANDER L. CLEMONS

June 16, 2023

INTELLECTUAL CAPITAL EQUITY

understanding of the facts and circumstances surrounding this matter, my review of the produced documentation, testimony, third party information available to date, and any underlying assumptions upon which I have relied. The information in this report is based on discovery to date and information that is currently available to me. Accordingly, my opinions described herein should be considered preliminary and subject to change based on future discovery, the testimony of other experts, and other case developments. I reserve the right to submit a supplemental report if both necessary and allowed by the Court. In addition to this report, I may rely on excerpts taken from videotaped depositions and/or demonstrative exhibits that illustrate the concepts and conclusions contained in this report.

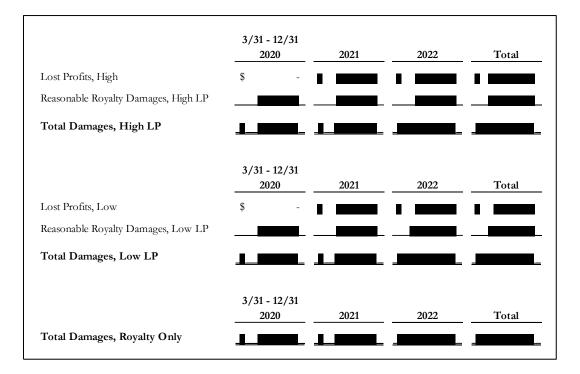
3 SUMMARY OF OPINIONS

Based on the totality of the circumstances in this case and the information available to me at this time, I have concluded that the appropriate form of compensation in this case is an award of lost profits damages, with reasonable royalties on any residual sales; however, I have also performed an analysis of reasonable royalty damages on all sales as an alternative.¹⁴

Regarding lost profits, I have analyzed each of the *Panduit* factors and have reached a conclusion regarding the lost profits that Invitae would have realized, but for Natera's infringement of the Patents-in-Suit. I have calculated both a high and low lost profits amount as further described below. Regarding reasonable royalties, in addition to or as an alternative to lost profits, I have analyzed quantitative and qualitative valuation metrics, including the *Georgia-Pacific* factors, and have reached a conclusion regarding the appropriate reasonable royalties due to Invitae for Natera's use of the Patents-in-Suit in connection with the Accused Product. As summarized in the figure below, I have calculated total damages, both including and excluding lost profits.

¹⁴ I note that my damages calculations assume that all of the Patents-in-Suit will be found to be valid and infringed. However, in the event that any Patents-in-Suit are found to be either invalid or not infringed, it would be straightforward to recalculate damages starting at the earliest issuance date of any remaining patents.

Figure 1: Summary of Damages through 2022¹⁵



I reserve the right to update my damages calculations if updated sales information is provided.

RELEVANT PARTIES 4

4.1 Invitae



Founded in 2010 and headquartered in San Francisco, California, Invitae INVITAE Corporation, is "a medical genetics company[] that provides genetic information to improve healthcare of people in the United States, Canada, and

internationally."16 Invitae "offers genetic tests in various clinical areas, including hereditary cancer, precision oncology, women's health, rare diseases, and pharmacogenomics; digital health solutions; and health data

¹⁵ Appendix 3.1.

^{16 &}quot;Invitae Corporation – Public Company Profile," S&P Capital IQ, capitaliq.com/CIQDotNet/company.aspx?companyId=222707176. I understand that the company was formerly known as Locus Development, Inc., and changed its name to Invitae Corporation in 2012.

INTELLECTUAL CAPITAL EQUITY

naïve assay "liked the convenience of needing no tissue biopsy (which can be hard to obtain for some patients)."¹⁷³ However, pharmaceutical companies that purchased Signatera have already revealed their preference for the higher sensitivity and specificity of a tumor-informed test, rather than the convenience of a tumor-naïve test, through their selection of Signatera rather than Reveal in the real world. This indicates that such customers are likely to purchase PCM, another tumor-informed test, rather than Reveal, a tumor-naïve test, in the but for world.

Taken together, the above analysis indicates that, in the absence of Natera's Signatera product, Invitae would have likely captured all of Signatera sales in the pharmaceutical market for MRD products; however, at a very minimum, Invitae would have split the sales roughly evenly with Guardant.

Based on the above, it is my understanding that there are no commercially acceptable non-infringing alternatives to the Patents-in-Suit for the Accused Products, it is my opinion that Invitae's PCM product would have captured all (but no less than 50%) of Signatera sales in the pharmaceutical market in the but for world, and the second *Panduit* factor is met.

9.3 Sufficient Capacity

The third prong of the *Panduit* test requires that a patentee demonstrate that it possessed sufficient manufacturing, marketing, and financial capacity to make the additional sales that it claims to have lost to the infringer.

Regarding manufacturing and marketing capacity, I understand that, because	ause of its robust testing and
marketing capabilities, Invitae could have sold its PCM product in place	of all of the infringing sales of
Signatera in the pharmaceutical market during the relevant lost profits da	amages period. ¹⁷⁴
Ac	lditionally, as discussed above in
Section 9.2, Mr. Moshkevich testified that	

¹⁷³ Alpert, Bill, "How Natera Is Defending Its Lead in a \$15B Cancer-Testing Market," *Barron's*, June 22, 2021, https://www.barrons.com/articles/natera-stock-cancer-testing-market-51624372368.

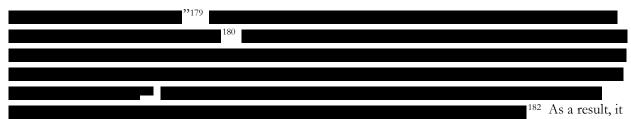
¹⁷⁴ Discussion with Richard Lusk; Discussion with Jim Stuart. I understand that Invitae's lost profits damages do not start until the date of Invitae's acquisition of the Patents-in-Suit on March 13, 2021.

¹⁷⁵ Deposition of Jim Stuart, April 6, 2023, pp. 6-7, 129.

¹⁷⁶ Deposition of Jim Stuart, April 6, 2023, p. 130.

¹⁷⁷ Deposition of Richard Lusk, June 9, 2023, pp. 8, 116.

¹⁷⁸ Deposition of Solomon Moshkevich, May 23, 2023, pp. 13, 155-156.



is clear that Invitae has sufficient manufacturing and marketing capacity to capture all of its lost PCM sales to Signatera in the pharmaceutical market during the relevant lost profits damages period. 183

Regarding financial capacity, it is my understanding that Invitae would not need to make any significant capital expenditures to increase its manufacturing or marketing capacity in order to capture its lost sales, due to its existing sufficient capacity. 184

Based on the above, it is my opinion that Invitae had sufficient capacity to satisfy 100% of the demand for Signatera in the pharmaceutical market during the relevant lost profits damages period, and the third Panduit factor is met.

9.4 Quantification

The final prong of the Panduit test requires the patent holder to properly quantify the amount of lost profits it suffered due to the infringement.

I understand that Invitae's lost profits damages do not start until the date of Invitae's acquisition of the Patents-in-Suit on March 13, 2021. 185 As a result, I have not considered lost profits to Invitae before March 13, 2021.

As discussed above, but for Natera's sales of Signatera, Invitae would have likely captured all (but no less than 50%) of those sales in the pharmaceutical market with sales of its PCM product. To calculate Invitae's lost

https://patentcenter.uspto.gov/applications/17322610/assignments?application=; "17/322,587 | 3851.0380005: SEQUENCE ASSEMBLY - Assignments," USPTO,

https://patentcenter.uspto.gov/applications/17322587/assignments?application=.

¹⁷⁹ Deposition of Solomon Moshkevich, May 23, 2023, p. 148.

¹⁸⁰ Discussion with Richard Lusk.

¹⁸¹ Discussion with Jim Stuart.

¹⁸² Discussion with Jim Stuart.

¹⁸³ See, Appendix 5.3; Appendix 5.4.

¹⁸⁴ Discussion with Richard Lusk; Discussion with Jim Stuart.

¹⁸⁵ Invitae0000003173-188 at 173; "14/250,891 | 3851.0380003: SEQUENCE ASSEMBLY – Assignments," USPTO, https://patentcenter.uspto.gov/applications/14250891/assignments?application=; "17/322,610 | 3851.0380006: SEQUENCE ASSEMBLY - Assignments," USPTO,

profits from these sales, I first considered the revenue generated by Natera from sales of Signatera in the pharmaceutical market starting on March 13, 2021.¹⁸⁶

Regarding Natera's Signatera revenue categorization, I understand that Signatera CLIA is the commercial product used for direct patient care, ¹⁸⁷ Signatera RUO is used by pharmaceutical companies and academic partners and is distinct from CLIA, ¹⁸⁸ Signatera Prospective is a prospective trial that is a clinical trial that will track a patient sample forward looking, ¹⁸⁹ and Signatera CDx (companion diagnostics) is used by a pharmaceutical company to do testing related to a specific pharmaceutical that they are developing. ¹⁹⁰ Revenues from Signatera RUO, Prospective, and CDx are categorized under Signatera Pharma, ¹⁹¹ which is the pharmaceutical and clinical trials related to the Signatera product and also includes sales to academia and federal programs. ¹⁹²

In order to calculate Invitae's lost revenue, I first calculated Natera's Signatera revenue for the pharmaceutical market (i.e., sales categorized as Signatera Pharma), from March 13, 2021, through 2022. 193 I then applied Invitae's but-for market share of 100% (but no less than 50%) of Signatera sales in the pharmaceutical market, discussed above, to determine the amount of PCM revenue that was lost by Invitae as a result of Natera's infringing sales of Signatera. 194 My calculation of Invitae's lost revenue is shown in the following figure. 195

¹⁸⁶ Appendix 5.5.

¹⁸⁷ Deposition of David Bessette, February 9, 2023, p. 60.

¹⁸⁸ Deposition of David Bessette, February 9, 2023, pp. 61-62.

¹⁸⁹ Deposition of David Bessette, February 9, 2023, p. 93.

¹⁹⁰ Deposition of David Bessette, February 9, 2023, p. 62

¹⁹¹ NTRA-INVT-00419829, tab "Signatera Gross Profit", rows 31-33.

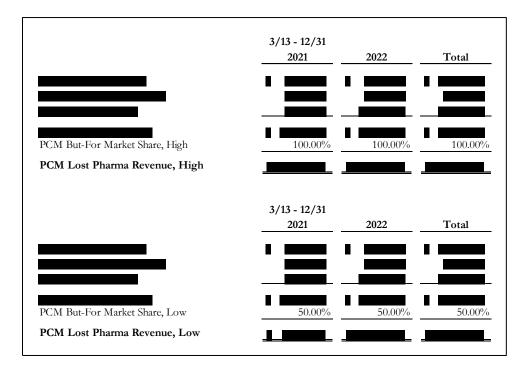
¹⁹² Deposition of David Bessette, February 9, 2023, pp. 128, 138.

¹⁹³ Appendix 5.5.

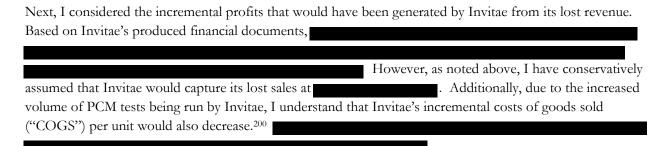
¹⁹⁴ Appendix 5.5.

¹⁹⁵ Appendix 5.5.

Figure 11: Invitae's Lost Revenues in the Pharmaceutical Market through 2022¹⁹⁶



I note that it is conservative to assume that Invitae would only generate as much revenue from its lost sales as Natera generated from its infringing sales in the pharmaceutical market, as Invitae's PCM product has historically had a higher ASP than Natera's Signatera product, in the pharmaceutical market.¹⁹⁷



¹⁹⁶ Appendix 5.5.

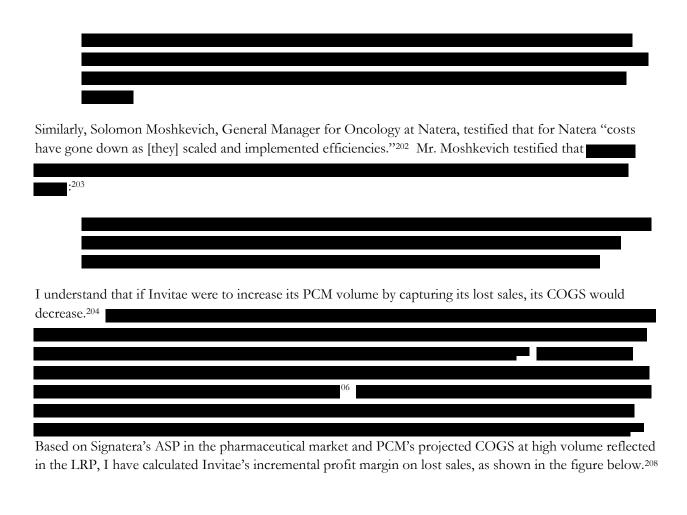
¹⁹⁷ Appendix 6.1; Appendix 6.2. See also, Deposition of Richard Lusk, June 9, 2023, Exhibit 5, tab "Segment Summary".

¹⁹⁸ Appendix 6.2; Invitae0000003349, and tab "2021-2022".

¹⁹⁹ Deposition of Richard Lusk, June 9, 2023, Exhibit 5, tab "Gross Margin Assumption".

²⁰⁰ Discussion with Richard Lusk.

²⁰¹ Deposition of Jim Stuart, April 6, 2023, pp. 6-7, 130-131.



²⁰² Deposition of Solomon Moshkevich, May 23, 2023, pp. 13, 109.

²⁰³ Deposition of Solomon Moshkevich, May 23, 2023, p. 111.

²⁰⁴ Discussion with Richard Lusk.

²⁰⁵ Deposition of Richard Lusk, June 9, 2023, pp. 84, 87-88, 108

Deposition of Richard Lusk, June 9, 2023, Exhibit 5, tab "Gross Margin Assumption", row 18.

Deposition of Richard Lusk, June 9, 2023, pp. 24-26.

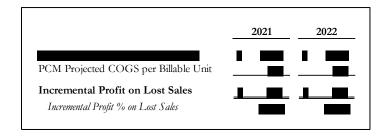
207 Appendix 5.4; Appendix 5.9; Deposition of Richard Lusk, June 9, 2023, Exhibit 5, tab "Growth Assumptions", row

Appendix 5.4; Appendix 5.9; Deposition of Richard Lusk, June 9, 2023, Exhibit 5, tab "Growth Assumptions", row 25.

Appendix 6.1.

²⁰⁸ Appendix 5.2.

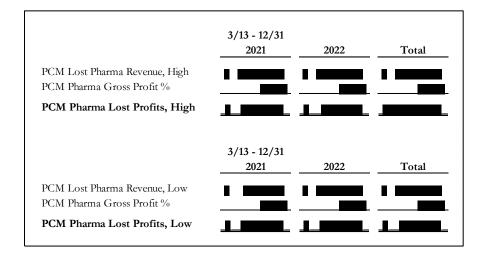
Figure 12: Invitae's Incremental Profit on Lost Sales²⁰⁹



Based on discussion with Richard Lusk, Vice President of Financial Planning and Analysis at Invitae, I understand that Invitae would not need to incur any additional incremental costs, apart from COGS to capture its lost sales.²¹⁰

Finally, I applied the gross profit margins calculated above to Invitae's lost revenue, in order to calculate Invitae's lost profits on their lost revenue, as shown in the following figure.²¹¹

Figure 13: Invitae's Lost Profits from Pharmaceutical Companies through 2022²¹²



Deposition of Richard Lusk, June 9, 2023, pp. 98-99.

²⁰⁹ Appendix 5.2. I note that the gross profit %s calculated above are . Appendix 6.1. ²¹⁰ Discussion with Richard Lusk.

²¹¹ Appendix 5.1.

²¹² Appendix 5.1.

Based on the above analysis of the *Panduit* factors, it is my opinion that, but for Natera's infringement of the Patents-in-Suit, Invitae would have realized lost profits, as calculated in the figure above.

For those sales of the Accused Product not accounted for in my calculation of Invitae's lost profits, I have calculated the reasonable royalty due on the residual sales in Section 13 below.

REASONABLE ROYALTY COMPENSATION

10.1 Overview

10

It is my understanding that in accordance with applicable statutory law, upon a finding of liability in a patent infringement action, the patentee is entitled to no less than "a reasonable royalty for the use made of the invention by the infringer[.]"²¹³

My determination of a reasonable royalty begins with the conclusion that there is no established royalty rate for the Patents-in-Suit. In general, a determination of whether there is an established royalty is based on a review of any relevant agreements produced and transactions relative to the following criteria defined in the *Sun Studs Inc. v. ATA Inc.* case:²¹⁴

- The agreements must have been entered into prior to when infringement began.
- The rate must not have been paid under threat of suit or in settlement of litigation.
- The rate must be paid for comparable rights.
- The rate must be paid by enough parties to indicate it is reasonable.

It is my opinion that there is no established royalty rate for the patented technology. Therefore, in the absence of an established royalty, I have based my determination of a reasonable royalty on a hypothetical negotiation between a willing licensee and a willing licensor around the time the alleged infringement began (the hypothetical negotiation date). The parties to the negotiation would have assumed that the Patents-in-Suit were valid and would be infringed by the prospective licensee unless he/she obtained a license. The reasonable royalty analysis focuses on the economic and bargaining positions of the plaintiff and defendant at the time of the hypothetical negotiation and the likely outcome of such negotiation given their positions.

This is consistent with the definition in the *Georgia-Pacific* case, specifically, "[t]he amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount which a prudent licensee—who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention—would have been willing to pay as a royalty and yet be

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²¹³ 35 U.S.C. § 284.

²¹⁴ Sun Studs, Inc. v. ATA Equip. Leasing, Inc., 872 F.2d. 978, 993 (Fed. Cir. 1989).

INTELLECTUAL CAPITAL EQUITY

royalties, in addition to or as an alternative to lost profits, I have analyzed quantitative and qualitative valuation metrics, including the *Georgia-Pacific* factors, and have reached a conclusion regarding the appropriate reasonable royalties due to Invitae for Natera's use of the Patents-in-Suit in connection with the Accused Product. As summarized in the figure below, I have calculated total damages, both including and excluding lost profits.

Figure 26: Summary of Damages through 2022⁵¹¹

I reserve the right to update my damages calculations if updated sales information is provided.

16 SIGNATURE

Respectfully submitted,

Alexander L. Clemons

June 16, 2023

Date

⁵¹¹ Appendix 3.1.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION OF AMERICA HOLDINGS,)
Plaintiff,)
) C.A. No. 21-669 (GBW)
V.)
NATERA, INC.)))
Defendant.)
LABORATORY CORPORATION OF AMERICA HOLDINGS,)))
Plaintiff,)
v.) C.A. No. 21-1635 (GBW)
NATERA, INC.))
Defendant.)

PLAINTIFF'S REPLY IN SUPPORT OF ITS MOTION IN LIMINE NO. 3: TO EXCLUDE EVIDENCE AND ARGUMENT REGARDING INVITAE'S OVERALL FINANCIAL CONDITION

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Attorneys for Plaintiff Laboratory Corporation of America Holdings Natera argues that Invitae's overall financial condition is relevant to rebut Labcorp's arguments on lost profits and commercial success. Opp. at 1.

As to lost profits, however, neither party's expert discussed Invitae's financial state in their damages opinions, whether for lost profits (including manufacturing capacity for "additional sales opportunities") or otherwise. Br. at 1; Opp. at 3. This makes sense, because Invitae's overall financial condition and bankruptcy do not bear on its ability to manufacture or market its product, Br. at 2, a point that renders Natera's case law irrelevant, Opp. at 1–2. Certainly, Natera has no evidence to suggest otherwise; if it did, its expert surely would have said so.

Second, and similarly, no party's expert has asserted that Invitae's overall financial condition shows commercial success of the Asserted Patents. In *Google*, the court explained that evidence of a party's "lack of commercial success *may be* probative evidence to *rebut* a showing of commercial success." *Personalized User Model, L.L.P. v. Google Inc.*, No. 09-cv-525-LPS, 2014 WL 807736, at *3 (D. Del. Feb. 27, 2014) (emphasis added). But because neither party's experts used Invitae's overall financial condition to argue commercial success, there is nothing to rebut. And *Apex*—a securities fraud case—is wholly inapposite. *APEX Fin. Options, LLC v. Gilbertson*, No. 19-cv-46-WCB-SRF, 2022 WL 622130, at *1 (D. Del. Mar. 3, 2022).

Natera further argues that the jury would be confused if it cannot discuss Invitae's financial condition, because "all the evidence about the plaintiff is referring to Invitae." Opp. at 3. But Invitae's overall financial condition is unnecessary to explain to the jury that the identity of the plaintiff changed from Invitae to Labcorp because Labcorp bought Invitae. Natera's insistence on referring to Invitae's bankruptcy is just an attempt to prejudicially paint Invitae in a bad light.

Invitae's financial condition remains irrelevant to any claim in this case and introducing it would be highly prejudicial. Br. at 2–3. Labcorp's motion should be granted.

August 13, 2025

Respectfully submitted,

FARNAN LLP

/s/ Brian E. Farnan

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Attorneys for Plaintiff Laboratory Corporation of America Holdings

CERTIFICATE OF SERVICE

I, Brian E. Farnan, hereby certify that on August 13, 2025, a copy of PLAINTIFF'S REPLY IN SUPPORT OF ITS MOTION IN LIMINE NO. 3: TO EXCLUDE EVIDENCE AND ARGUMENT REGARDING INVITAE'S OVERALL FINANCIAL CONDITION was served on the following as indicated:

Via E-Mail

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Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 573 of 739 PageID

EXHIBIT 20A

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION OF
AMERICA HOLDINGS,

Plaintiff,

C.A. No. 21-cv-669-GBW

v.

NATERA, INC.,

Defendant.

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

C.A. No. 21-cv-1635-GBW

DEFENDANT'S MOTION *IN LIMINE* NO. 1: PRECLUDE EVIDENCE OR ARGUMENT THAT ANTICIPATION BY A PRIOR ART SYSTEM CANNOT BE ESTABLISHED USING MULTIPLE DOCUMENTS THAT DESCRIBE THE SYSTEM

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I. INTRODUCTION

Natera respectfully moves to preclude Invitae from offering evidence or argument suggesting that anticipation by a prior-art system cannot be established through multiple documents describing that system. Such evidence and argument by Invitae would misstate the law and would thus be irrelevant, prejudicial, and likely to confuse and mislead the jury. *See* Fed. R. Evid. 402 & 403.

II. BACKGROUND

The Asserted Patents cover a computerized algorithm, *see*, *e.g.*, Ex. A at 61:3–14, for assembling and comparing genetic data. Some of the prior art on which Natera relies are software programs that pre-date the Asserted Patents. One such prior-art software is "NextGENe," which was the subject of Natera's motion for summary judgment of anticipation. *See* D.I. 224, 225. In opposing that motion, Invitae made the surprising (and previously undisclosed) argument that Natera's reliance on multiple documents to demonstrate NextGENe's functionality and features precludes a finding of anticipation because, Invitae argued, "[a]ll authorities on anticipation require a *single* prior art reference." D.I. 246 at 26 (emphasis in original). Invitae's argument seems to be that, even where the asserted prior art is a product or system (here, software) and not a printed publication, and the defendant relies on multiple documents to establish the functionality of that prior art—here, to prove what the software did and how it worked—the challenge is one of obviousness rather than anticipation. During a meet and confer, Invitae's counsel indicated that Invitae believes it is entitled to argue this position before the jury. But it would be a misstatement of the law to do so and should therefore be prohibited.¹

¹ Invitae also has never properly challenged whether the evidence proffered by Natera concerns the same prior art system, and it is too late now for that argument. Invitae's experts never opined that the documents Natera's experts use to demonstrate the functionality of a particular prior-art system do not, in fact, describe that system, and in the

III. ARGUMENT

Printed publications—patents, scientific papers, articles—are the most common form of prior art. Where anticipation rests on a printed publication, it is hornbook law that all elements of the claim must be found in one such printed document. But a patent claim can also be anticipated by something tangible that existed in the past—an air conditioner or blender, for example—or, as relevant here, a software program or system. In such circumstances, the pre-existing article is itself the single prior art reference. For example, under 35 U.S.C. § 102(a), the prior use or knowledge of an invention can anticipate an asserted patent claim. Likewise, under 35 U.S.C. § 102(g)(2), someone else's invention may anticipate a patent claim, whether or not it is made public, provided that it was not abandoned, suppressed, or concealed. *See Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 976–77 (Fed. Cir. 2014).

It is well settled that, where the prior art is a product or system, "it is permissible for a defendant to establish anticipation by using several documents that reveal how a single prior art system works." *IOENGINE, LLC v. PayPal Holdings, Inc.*, 607 F. Supp. 3d 464, 518–19 (D. Del. 2022); *see also Altera Corp. v. PACT XPP Techs., AG*, No. 14-02868-JD, 2015 WL 3830982, at *3 (N.D. Cal. June 19, 2015) ("Multiple documents that describe a single prior art device count as a single prior art reference."). That is because the system itself is the single piece of prior art that establishes a lack of novelty; the documents used to prove the system's functionality are simply evidence. *See, e.g., Sonoscan, Inc. v. Sonotek, Inc.*, 936 F.2d 1261, 1263 (Fed. Cir. 1991) ("That the offered product is in fact the claimed invention may be established by any relevant evidence, such as memoranda, drawings, correspondence, and testimony of witnesses." (citation omitted));

case of NextGENe, Invitae's expert admitted that they do. See Ex. B at 261:13–22. Nor has Invitae raised this argument in any of its interrogatory responses, including its validity-contention response. See Ex. C at 7–69. Invitae should not now be permitted to attempt to overcome this defect by presenting arguments to the jury that contradict the law.

see also British Telecomm. PLC v. IAC/InteractiveCorp., No. 18-366-WCB, 2020 WL 3047989, at *6 (D. Del. June 8, 2020) ("It was permissible for [the defendant] to use several documents as evidence about how a single prior art system worked."); Daedalus Blue, LLC v. MicroStrategy Inc., No. 20-551-RCY, 2023 WL 5941736, at *9 (E.D. Va. Sept. 12, 2023) ("For product-based anticipation . . . secondary materials about a product may be relied upon as evidence of how the prior art product works for anticipation purposes.").

Indeed, this Court has held that it is appropriate to rely on "executable software, [a] user manual, *and* source code" to show how a single prior-art system operated for purposes of proving anticipation. *See Finjan, Inc. v. Symantec Corp.*, No. 10-593-GMS, 2013 WL 5302560, at *12 (D. Del. Sept. 19, 2013) (emphasis added), *aff'd*, 577 F. App'x 999 (Fed. Cir. 2014).

In light of this overwhelming authority, Invitae should not be permitted to mislead or confuse the jury by suggesting that a prior art software system is *per se* not anticipatory because Natera relies on multiple sources to demonstrate the functionality and elements of the prior art software. Such argument is not only irrelevant as a matter of law but also misleading and confusing, as it would put before the jury a theory based on an erroneous legal standard. *See, e.g., Honeywell Int., Inc. v. Hamilton Sundstrand Corp.*, 378 F. Supp. 2d 459, 481–82 (D. Del. 2005) (excluding validity theory that applies the wrong legal standard under Rules 402 and 403). Natera respectfully moves the Court to preclude such evidence or argument from Invitae.

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 579 of 739 PageID

EXHIBIT A

	Page 1
1	VOLUME: I
	PAGES: 1-326
2	EXHIBITS: 1-33
3	UNITED STATES DISTRICT COURT
4	FOR THE DISTRICT OF DELAWARE
5	NO. 1:21-cv-01635-LPS
6	
7	
8	INVITAE CORPORATION,)
9	Plaintiff,)
10	vs.)
11	NATERA, INC.,
12	Defendant.)
13)
14	
15	VIDEOTAPED DEPOSITION OF INVITAE
16	CORPORATION BY GREGORY J. PORRECA, PhD, called as a
17	witness by and on behalf of the Defendant, pursuant
18	to the applicable provisions of the Federal Rules
19	of Civil Procedure, Rule 30(b)(6), before P. Jodi
20	Ohnemus (remotely), RPR, RMR, CRR, CA-CSR #13192,
21	NH-LSR #91, MA-CSR #123193, and Notary Public,
22	within and for the Commonwealth of Massachusetts,
23	at Cambridge, Massachusetts, on Friday, April 28,
24	2023, commencing at 9:47 a.m.
25	

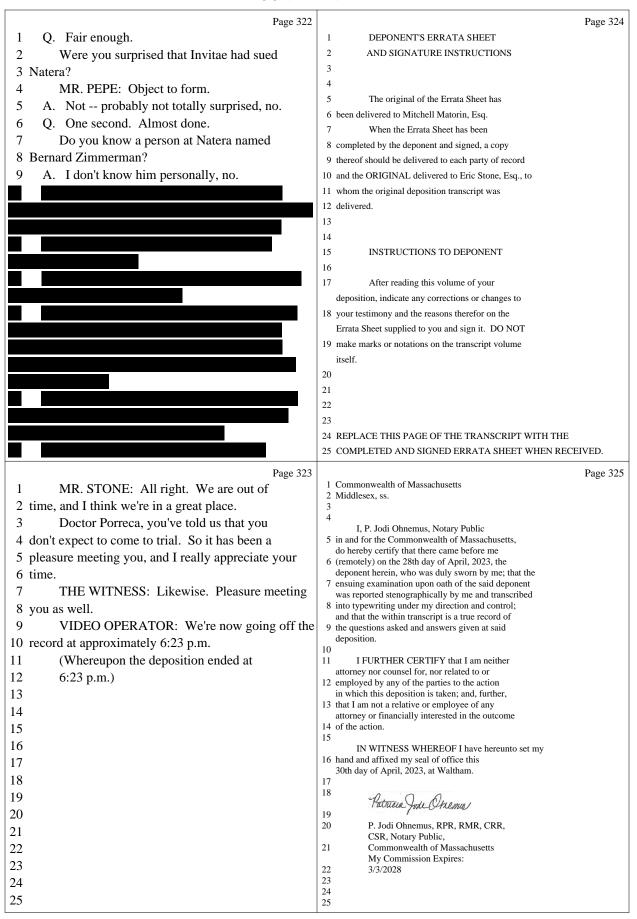
APPEARANCES: 2 1		Page 2			Page 4
2	1		1	INDEX	1 age 4
3					
WEIL, GOTSHAL & MANGES, LLP 4		(Via Videoconference)	3	TESTIMONY OF:	PAGE
6	4	· · · · · · · · · · · · · · · · · · ·	4		
6	5			GREGORY J. PORRECA	
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15	13		13		
16	14	(Via Videoconference)	14		
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24 25 25 25 25 25 25 25	22	Loop Biosolutions	22		
APPEARANCES: (CONT'D)	23		23		
1 APPEARANCES: (CONT'D)	24		24		
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3	1	APPEARANCES: (CONT'D)	1	EXHIBITS	
4 GROOMBRIDGE WU BAUGHMAN 4 Exhibit 1 Greg Porreca Linked-In 16 5 & STONE, LLP 5 profile 6 BY: Eric Stone, Esq. 6 Exhibit 2 US Patent 10,604,799 27 7 Ariella Barel, Esq. 7 Exhibit 3 email, 9/27/2011, 30 8 Daniel Klein, Esq. 8 ML-PORRECA0000000076-78 9 565 Fifth Avenue, Suite 2900 9 Exhibit 4 email, 9/28/2011, 46 10 New York, NY 10017 10 ML-PORRECA0000000080-81 11 11 332 269-0030 11 Exhibit 5 Invention Disclosure Form, 58 12 Eric.stone@groombridgewu.com 12 ML-PORRECA000000068-74 13 Ariella.barel@groombridgewu.com 13 Exhibit 6 US Patent, 11,149,308 153 14 Dan.klein@groombridgewu.com 14 Exhibit 7 US Patent 11,155,863 153 15 For the Defendants 15 Exhibit 8 US Patent 8,209,130 156 16 Ex	2		2	EXHIBIT DESCRIPTION	PAGE
5 & STONE, LLP 5 profile 6 BY: Eric Stone, Esq. 6 Exhibit 2 US Patent 10,604,799 27 7 Ariella Barel, Esq. 7 Exhibit 3 email, 9/27/2011, 30 30 8 Daniel Klein, Esq. 8 ML-PORRECA0000000076-78 46 9 565 Fifth Avenue, Suite 2900 9 Exhibit 4 email, 9/28/2011, 46 46 10 New York, NY 10017 10 ML-PORRECA0000000080-81 11 Exhibit 5 Invention Disclosure Form, 58 58 12 Eric.stone@groombridgewu.com 12 ML-PORRECA000000068-74 13 Exhibit 6 US Patent, 11,149,308 153 14 Dan.klein@groombridgewu.com 14 Exhibit 7 US Patent 11,155,863 153 15 For the Defendants 15 Exhibit 8 US Patent 8,209,130 156 16 Exhibit 9 US Patent 8,738,300 156 17 ALSO PRESENT: 17 Exhibit 10 Bio IT World 2011, Boston, 16 18 MA, ML-PORRECA00000001649, mu	3	(Via Videoconference)	3		
6 BY: Eric Stone, Esq. 6 Exhibit 2 US Patent 10,604,799 27 7 Ariella Barel, Esq. 7 Exhibit 3 email, 9/27/2011, 30 30 8 Daniel Klein, Esq. 8 ML-PORRECA0000000076-78 9 9 565 Fifth Avenue, Suite 2900 9 Exhibit 4 email, 9/28/2011, 46 46 10 New York, NY 10017 10 ML-PORRECA0000000080-81 11 Exhibit 5 Invention Disclosure Form, 58 12 Eric.stone@groombridgewu.com 12 ML-PORRECA0000000068-74 13 Exhibit 6 US Patent, 11,149,308 153 153 14 Dan.klein@groombridgewu.com 14 Exhibit 6 US Patent, 11,149,308 153 153 15 For the Defendants 15 Exhibit 7 US Patent 8,209,130 156 16 Exhibit 8 US Patent 8,209,130 156 17 ALSO PRESENT: 17 Exhibit 10 Bio IT World 2011, Boston, 16 18 (Via Videoconference) 18 MA, ML-PORRECA00000001649, 16 19	4	GROOMBRIDGE WU BAUGHMAN	I 4	Exhibit 1 Greg Porreca Linked-In	16
7 Ariella Barel, Esq. 7 Exhibit 3 email, 9/27/2011, 30 8 Daniel Klein, Esq. 8 ML-PORRECA00000000076-78 9 565 Fifth Avenue, Suite 2900 9 Exhibit 4 email, 9/28/2011, 46 10 New York, NY 10017 10 ML-PORRECA0000000080-81 11 332 269-0030 11 Exhibit 5 Invention Disclosure Form, 58 12 Eric.stone@groombridgewu.com 12 ML-PORRECA000000068-74 13 Ariella.barel@groombridgewu.com 13 Exhibit 6 US Patent, 11,149,308 153 15 For the Defendants 15 Exhibit 7 US Patent 8,209,130 156 16 Exhibit 8 US Patent 8,738,300 156 17 ALSO PRESENT: 17 Exhibit 10 Bio IT World 2011, Boston, 16 18 (Via Videoconference) 18 MA, ML-PORRECA0000001649, multipage document 20 Exhibit 11 email, 9/28/2011, 168 21 Invitae0010119047 22 Carissa Narciso, 22 Exhibit 12 DePristo, e	5	·	5	profile	
8 Daniel Klein, Esq. 8 ML-PORRECA00000000076-78 9 565 Fifth Avenue, Suite 2900 9 Exhibit 4 email, 9/28/2011, 46 10 New York, NY 10017 10 ML-PORRECA0000000080-81 11 332 269-0030 11 Exhibit 5 Invention Disclosure Form, 58 12 Eric.stone@groombridgewu.com 12 ML-PORRECA000000068-74 13 Ariella.barel@groombridgewu.com 13 Exhibit 6 US Patent, 11,149,308 153 15 For the Defendants 15 Exhibit 7 US Patent 8,209,130 156 16 16 Exhibit 8 US Patent 8,209,130 156 17 ALSO PRESENT: 17 Exhibit 10 Bio IT World 2011, Boston, 16 18 (Via Videoconference) 18 MA, ML-PORRECA0000001649, 19 Kevin Gallagher, Video Operator 19 multipage document 20 Exhibit 11 email, 2/13/2011, 168 21 Invitae0010119047 22 Exhibit 12 DePristo, et al., 168	6	BY: Eric Stone, Esq.	6	Exhibit 2 US Patent 10,604,799	27
9 565 Fifth Avenue, Suite 2900 10 New York, NY 10017 11 332 269-0030 12 Eric.stone@groombridgewu.com 13 Ariella.barel@groombridgewu.com 14 Dan.klein@groombridgewu.com 15 For the Defendants 16 (Via Videoconference) 19 Kevin Gallagher, Video Operator 20 (Via Videoconference) 21 (Via Videoconference) 22 Carissa Narciso, 2 (Stabilit 2 (Stabilit 4 (mail, 9/28/2011, 46	7	Ariella Barel, Esq.	7	Exhibit 3 email, 9/27/2011,	30
10 New York, NY 10017 10 ML-PORRECA0000000080-81 11 332 269-0030 11 Exhibit 5 Invention Disclosure Form, 58 12 Eric.stone@groombridgewu.com 12 ML-PORRECA000000068-74 13 Ariella.barel@groombridgewu.com 13 Exhibit 6 US Patent, 11,149,308 153 14 Dan.klein@groombridgewu.com 14 Exhibit 7 US Patent 11,155,863 153 15 For the Defendants 15 Exhibit 8 US Patent 8,209,130 156 16 Exhibit 9 US Patent 8,738,300 156 17 Exhibit 10 Bio IT World 2011, Boston, 16 18 (Via Videoconference) 18 MA, ML-PORRECA0000001649, 19 multipage document 20 Exhibit 11 email, 2/13/2011, 168 21 (Via Videoconference) 21 Invitae0010119047 22 Carissa Narciso, 22 Exhibit 12 DePristo, et al., 168	8	· •	8	ML-PORRECA0000000076	5-78
11 332 269-0030 11 Exhibit 5 Invention Disclosure Form, 58 12 Eric.stone@groombridgewu.com 12 ML-PORRECA0000000068-74 13 Ariella.barel@groombridgewu.com 13 Exhibit 6 US Patent, 11,149,308 153 14 Dan.klein@groombridgewu.com 14 Exhibit 7 US Patent 11,155,863 153 15 For the Defendants 15 Exhibit 8 US Patent 8,209,130 156 16 16 Exhibit 9 US Patent 8,738,300 156 17 ALSO PRESENT: 17 Exhibit 10 Bio IT World 2011, Boston, 16 18 (Via Videoconference) 18 MA, ML-PORRECA00000001649, 19 Kevin Gallagher, Video Operator 19 multipage document 20 Exhibit 11 email, 2/13/2011, 168 21 (Via Videoconference) 21 Invitae0010119047 22 Exhibit 12 DePristo, et al., 168	9	565 Fifth Avenue, Suite 2900	9	Exhibit 4 email, 9/28/2011,	46
12 Eric.stone@groombridgewu.com 12 ML-PORRECA0000000068-74 13 Ariella.barel@groombridgewu.com 13 Exhibit 6 US Patent, 11,149,308 153 14 Dan.klein@groombridgewu.com 14 Exhibit 7 US Patent 11,155,863 153 15 For the Defendants 15 Exhibit 8 US Patent 8,209,130 156 16 Exhibit 9 US Patent 8,738,300 156 17 ALSO PRESENT: 17 Exhibit 10 Bio IT World 2011, Boston, 16 18 (Via Videoconference) 18 MA, ML-PORRECA0000001649, 19 19 Kevin Gallagher, Video Operator 19 multipage document 20 20 Exhibit 11 email, 2/13/2011, 168 21 (Via Videoconference) 21 Invitae0010119047 22 Carissa Narciso, 22 Exhibit 12 DePristo, et al., 168	10	New York, NY 10017	10	ML-PORRECA000000080-	81
13 Ariella.barel@groombridgewu.com 13 Exhibit 6 US Patent, 11,149,308 153 14 Dan.klein@groombridgewu.com 14 Exhibit 7 US Patent 11,155,863 153 15 For the Defendants 15 Exhibit 8 US Patent 8,209,130 156 16 Exhibit 9 US Patent 8,738,300 156 17 ALSO PRESENT: 17 Exhibit 10 Bio IT World 2011, Boston, 16 18 (Via Videoconference) 18 MA, ML-PORRECA00000001649, 19 Kevin Gallagher, Video Operator 19 multipage document 20 Exhibit 11 email, 2/13/2011, 168 21 (Via Videoconference) 21 Invitae0010119047 22 Carissa Narciso, 22 Exhibit 12 DePristo, et al., 168	11		11	Exhibit 5 Invention Disclosure For	m, 58
14 Dan.klein@groombridgewu.com 14 Exhibit 7 US Patent 11,155,863 153 15 For the Defendants 15 Exhibit 8 US Patent 8,209,130 156 16 16 Exhibit 9 US Patent 8,738,300 156 17 ALSO PRESENT: 17 Exhibit 10 Bio IT World 2011, Boston, 16 18 (Via Videoconference) 18 MA, ML-PORRECA0000001649, 19 multipage document 20 Exhibit 11 email, 2/13/2011, 168 21 (Via Videoconference) 21 Invitae0010119047 22 Carissa Narciso, 22 Exhibit 12 DePristo, et al., 168			12		74
15 For the Defendants 15 Exhibit 8 US Patent 8,209,130 156 16 16 Exhibit 9 US Patent 8,738,300 156 17 ALSO PRESENT: 17 Exhibit 10 Bio IT World 2011, Boston, 16 18 (Via Videoconference) 18 MA, ML-PORRECA0000001649, 19 19 multipage document 20 Exhibit 11 email, 2/13/2011, 168 21 (Via Videoconference) 21 Invitae0010119047 22 Carissa Narciso, 22 Exhibit 12 DePristo, et al., 168			13		
16 16 Exhibit 9 US Patent 8,738,300 156 17 ALSO PRESENT: 17 Exhibit 10 Bio IT World 2011, Boston, 16 18 (Via Videoconference) 18 MA, ML-PORRECA00000001649, 19 19 multipage document 20 Exhibit 11 email, 2/13/2011, 168 21 (Via Videoconference) 21 Invitae0010119047 22 Carissa Narciso, 22 Exhibit 12 DePristo, et al., 168			14		
17 ALSO PRESENT: 17 Exhibit 10 Bio IT World 2011, Boston, 16 18 (Via Videoconference) 18 MA, ML-PORRECA00000001649, 19 19 Kevin Gallagher, Video Operator 20 19 multipage document 20 Exhibit 11 email, 2/13/2011, 168 21 (Via Videoconference) 22 Carissa Narciso, 21 Invitae0010119047 22 Exhibit 12 DePristo, et al., 168		For the Defendants	15		
18 (Via Videoconference) 18 MA, ML-PORRECA0000001649, 19 Kevin Gallagher, Video Operator 19 multipage document 20 20 Exhibit 11 email, 2/13/2011, 168 21 (Via Videoconference) 21 Invitae0010119047 22 Carissa Narciso, 22 Exhibit 12 DePristo, et al., 168			16	, ,	
19 Kevin Gallagher, Video Operator 20 20 Exhibit 11 email, 2/13/2011, 168 21 (Via Videoconference) 21 Invitae0010119047 22 Carissa Narciso, 22 Exhibit 12 DePristo, et al., 168					
20 20 Exhibit 11 email, 2/13/2011, 168 21 Invitae0010119047 22 Carissa Narciso, 22 Exhibit 12 DePristo, et al., 168		·)1649,
21 (Via Videoconference) 21 Invitae0010119047 22 Carissa Narciso, 22 Exhibit 12 DePristo, et al., 168		Kevin Gallagher, Video Operator			
22 Carissa Narciso, 22 Exhibit 12 DePristo, et al., 168					168
23 Veritext Concierge 23 manuscript. 20-page document				· · · · · · · · · · · · · · · · · · ·	
	23	Veritext Concierge	23	manuscript, 20-page docume	
24 Exhibit 13 email, 1/13/2011, 175					175
25 Invitae0010118439	25		25	Invitae0010118439	

2 (Pages 2 - 5)

	Page 6	Page 8
1	Exhibit 14 NextGENe, Manion, et al., 175	1 VIDEO OPERATOR: We are now going on the
2	February 2009,	2 record at approximately 9:47 a.m. Today's date is
3	Invitae0010118440-442	3 April 28th, 2023. This is media unit No. 1 in the
4	Exhibit 15 NextGENe, Levan, et al., 175	4 video-recorded deposition of Gregory Porreca, taken
5	September 2008	5 in the matter of Invitae Corporation versus Natera,
6	Exhibit 16 email, 8/19/2009, 187	6 Inc. It is filed in the US District Court for the
7	Invitae0010122472-474	7 District of Delaware. I have two case numbers: CA
8	Exhibit 17 email, 2/12/2013, 196	8 No. 21-669 and CA No. 21-1634 35, rather.
9	Invitae0010111931-932	9 My name is Kevin Gallagher. I am the
10	Exhibit 18 email, 3/18/2014, 199	10 court I am the videographer. The court reporter
11	Invitae0010091296	11 is Jodi Ohnemus, and the concierge is Carissa
12	Exhibit 19 abstract, Kennedy, et al., 201	12 Narcisco. We're all from the firm of Veritext
13	Invitae0010091297-298	13 Legal Solutions.
14	Exhibit 20 article, Umbarger, et al., 206	14 At this time the attorneys present in the
15	ML-PORRECA00000001584-592	15 deposition will identify themselves and their
16	Exhibit 21 email, 2/8/2013, 220	16 affiliations for the record.
17	Invitae0010135520-521	MR. STONE: Sure. My name is Eric Stone.
18	Exhibit 22 Overview of MIP Technology, 224	18 I'm with the firm of Groombridge Wu Baughman &
19	1/27/2017,	19 Stone. I'm joined today by my colleagues Ariella
20	Invitae0010126923-939	20 Barel and Dan Klein and together we represent
21	Exhibit 23 letter, Jeffrey Luber, 230	21 Natera.
22	3/16/2017, five-page	MR. PEPE: Chris Pepe from Weil Gotshal,
23	document	23 representing Invitae and the witness.
24	Exhibit 24 Description of Technology, 242	MR. MATORIN: Mitchell Matorin, Matorin
25	Invitae0010126595-597	25 Law Office in Wellesley, Massachusetts,
	Page 7	Page 9
1	Exhibit 25 email, 3/5/2017, 243	1 representing both the witness and Molecular Loop.
2	Invitae0010126590-594	2 VIDEO OPERATOR: And now our court
3	Exhibit 26 Good Start Genetics 267	3 reporter will swear or affirm the witness and we
4	Intellectual Property	4 can proceed.
5	Overview	5 GREGORY J. PORRECA, PhD, having
6	Invitae0010126201-215	6 satisfactorily been identified by
7	Exhibit 27 Agreement and Plan of 271	7 the production of a driver's license,
8	Merger, 118-page document	8 and being first duly sworn by the Notary
9	Exhibit 28 email, 12/18/2017, 276	9 Public, was examined and testified as
10	Invitae0000003686-689	follows to interrogatories.
11	E 1 11 1 20 G 1 G 1 G 1 T 1 T 1 T 1 T 1 T 1 T 1 T 1	
	Exhibit 29 Sale of MIP Assets to 281	11 COURT REPORTER: Thank you. Go right
12	Molecular Loop Biosolutions,	12 ahead.
12 13	Molecular Loop Biosolutions, LLC, Invitae0000003121-169	12 ahead.13 MR. STONE: I will. I actually have a
12 13 14	Molecular Loop Biosolutions, LLC, Invitae0000003121-169 Exhibit 30 First Amendment to Asset 293	 12 ahead. 13 MR. STONE: I will. I actually have a 14 preliminary question for counsel which I was going
12 13 14 15	Molecular Loop Biosolutions, LLC, Invitae0000003121-169 Exhibit 30 First Amendment to Asset 293 Purchase Agreement,	 12 ahead. 13 MR. STONE: I will. I actually have a 14 preliminary question for counsel which I was going 15 to jump in and do before the witness was sworn;
12 13 14 15 16	Molecular Loop Biosolutions, LLC, Invitae0000003121-169 Exhibit 30 First Amendment to Asset 293 Purchase Agreement, Invitae00000003101-102	12 ahead. 13 MR. STONE: I will. I actually have a 14 preliminary question for counsel which I was going 15 to jump in and do before the witness was sworn; 16 but, you know, I didn't want to talk over you.
12 13 14 15 16 17	Molecular Loop Biosolutions, LLC, Invitae0000003121-169 Exhibit 30 First Amendment to Asset 293 Purchase Agreement, Invitae0000003101-102 Exhibit 31 Third Amendment to Asset 293	12 ahead. 13 MR. STONE: I will. I actually have a 14 preliminary question for counsel which I was going 15 to jump in and do before the witness was sworn; 16 but, you know, I didn't want to talk over you. 17 I don't care which of you defends the
12 13 14 15 16 17 18	Molecular Loop Biosolutions, LLC, Invitae0000003121-169 Exhibit 30 First Amendment to Asset 293 Purchase Agreement, Invitae0000003101-102 Exhibit 31 Third Amendment to Asset 293 Purchase Agreement,	12 ahead. 13 MR. STONE: I will. I actually have a 14 preliminary question for counsel which I was going 15 to jump in and do before the witness was sworn; 16 but, you know, I didn't want to talk over you. 17 I don't care which of you defends the 18 deposition, but I don't want to play Canadian
12 13 14 15 16 17 18 19	Molecular Loop Biosolutions, LLC, Invitae0000003121-169 Exhibit 30 First Amendment to Asset 293 Purchase Agreement, Invitae0000003101-102 Exhibit 31 Third Amendment to Asset 293 Purchase Agreement, Invitae00000003105-106	12 ahead. 13 MR. STONE: I will. I actually have a 14 preliminary question for counsel which I was going 15 to jump in and do before the witness was sworn; 16 but, you know, I didn't want to talk over you. 17 I don't care which of you defends the 18 deposition, but I don't want to play Canadian 19 doubles. Which of you is going to be playing the
12 13 14 15 16 17 18 19 20	Molecular Loop Biosolutions, LLC, Invitae0000003121-169 Exhibit 30 First Amendment to Asset 293 Purchase Agreement, Invitae0000003101-102 Exhibit 31 Third Amendment to Asset 293 Purchase Agreement, Invitae00000003105-106 Exhibit 32 email, 8/7/2020, 304	12 ahead. 13 MR. STONE: I will. I actually have a 14 preliminary question for counsel which I was going 15 to jump in and do before the witness was sworn; 16 but, you know, I didn't want to talk over you. 17 I don't care which of you defends the 18 deposition, but I don't want to play Canadian 19 doubles. Which of you is going to be playing the 20 primary role in defending?
12 13 14 15 16 17 18 19 20 21	Molecular Loop Biosolutions, LLC, Invitae0000003121-169 Exhibit 30 First Amendment to Asset 293 Purchase Agreement, Invitae0000003101-102 Exhibit 31 Third Amendment to Asset 293 Purchase Agreement, Invitae00000003105-106 Exhibit 32 email, 8/7/2020, 304 Invitae00000003205-206	12 ahead. 13 MR. STONE: I will. I actually have a 14 preliminary question for counsel which I was going 15 to jump in and do before the witness was sworn; 16 but, you know, I didn't want to talk over you. 17 I don't care which of you defends the 18 deposition, but I don't want to play Canadian 19 doubles. Which of you is going to be playing the 20 primary role in defending? 21 MR. PEPE: I will.
12 13 14 15 16 17 18 19 20 21 22	Molecular Loop Biosolutions, LLC, Invitae0000003121-169 Exhibit 30 First Amendment to Asset 293 Purchase Agreement, Invitae0000003101-102 Exhibit 31 Third Amendment to Asset 293 Purchase Agreement, Invitae00000003105-106 Exhibit 32 email, 8/7/2020, 304 Invitae0000003205-206 Exhibit 33 Asset Purchase Agreement, 317	12 ahead. 13 MR. STONE: I will. I actually have a 14 preliminary question for counsel which I was going 15 to jump in and do before the witness was sworn; 16 but, you know, I didn't want to talk over you. 17 I don't care which of you defends the 18 deposition, but I don't want to play Canadian 19 doubles. Which of you is going to be playing the 20 primary role in defending? 21 MR. PEPE: I will. 22 MR. STONE: That's fine. Totally okay.
12 13 14 15 16 17 18 19 20 21 22 23	Molecular Loop Biosolutions, LLC, Invitae0000003121-169 Exhibit 30 First Amendment to Asset 293 Purchase Agreement, Invitae0000003101-102 Exhibit 31 Third Amendment to Asset 293 Purchase Agreement, Invitae0000003105-106 Exhibit 32 email, 8/7/2020, 304 Invitae0000003205-206 Exhibit 33 Asset Purchase Agreement, 317 3/13/2021,	12 ahead. 13 MR. STONE: I will. I actually have a 14 preliminary question for counsel which I was going 15 to jump in and do before the witness was sworn; 16 but, you know, I didn't want to talk over you. 17 I don't care which of you defends the 18 deposition, but I don't want to play Canadian 19 doubles. Which of you is going to be playing the 20 primary role in defending? 21 MR. PEPE: I will. 22 MR. STONE: That's fine. Totally okay. 23 MR. PEPE: Just note there may be times
12 13 14 15 16 17 18 19 20 21 22	Molecular Loop Biosolutions, LLC, Invitae0000003121-169 Exhibit 30 First Amendment to Asset 293 Purchase Agreement, Invitae0000003101-102 Exhibit 31 Third Amendment to Asset 293 Purchase Agreement, Invitae00000003105-106 Exhibit 32 email, 8/7/2020, 304 Invitae0000003205-206 Exhibit 33 Asset Purchase Agreement, 317	12 ahead. 13 MR. STONE: I will. I actually have a 14 preliminary question for counsel which I was going 15 to jump in and do before the witness was sworn; 16 but, you know, I didn't want to talk over you. 17 I don't care which of you defends the 18 deposition, but I don't want to play Canadian 19 doubles. Which of you is going to be playing the 20 primary role in defending? 21 MR. PEPE: I will. 22 MR. STONE: That's fine. Totally okay.

Page 58	Page 60
1 A. Yes. This would be the first diagram of	1 A. Tom Meyers was our IP attorney at the time
2 the algorithm.	2 for the company.
3 Q. Let's look at Exhibit 5 to your	3 Q. In house or outside counsel?
4 deposition, and then I'm going to want a break in a	4 A. Outside counsel.
5 minute 'cause I can hear my voice going. But let's	5 Q. And it says (as read):
6 look at Exhibit 5 for a moment.	6 "On what date did you make such a
7 (Exhibit 5, Invention Disclosure Form,	7 disclosure?"
8 ML-PORRECA000000068-74.)	8 Answer: "September 28, 2011."
9 A. Okay.	9 You see that?
10 Q. Doctor Porreca, I've placed before you	10 A. I do see that.
11 what I've marked as Exhibit 5 to your deposition,	11 Q. Fair to say, then, that you had the idea
12 which bears the Bates numbers ML-PORRECA 68 through	12 on September 27, 2011, and were in a position to
13 74. It's a document entitled "Invention Disclosure	13 disclose the idea to your lawyer the next day?
14 Form."	14 A. That's what this document indicates.
Do you see that there?	15 Q. Is it right?
16 A. I do.	16 A. As far as I can remember, I believe it is
17 Q. It lists as the people who conceived of	17 correct.
18 and/or reduced to practice the invention, yourself	18 Q. On the top of the next page it says (as
19 and Doctor Kennedy; correct?	19 read):
20 A. That is correct.	20 "When did you first do any experimental
21 Q. And then there is a section entitled	21 work towards carrying out the invention?"
22 "Description of the Invention"?	22 You see that there?
23 A. Yes.	23 A. I do.
24 Q. And that continues on for a couple of	24 Q. And the answer is "N/A."
25 pages; and on page 4 of this document actually has	25 A. Yes.
Page 59	Page 61
1 the photograph of the whiteboard; correct?	1 Q. Is that meaning not applicable?
2 A. That is correct.	2 A. Correct.
3 Q. Then it says (as read):	3 Q. And the reason that that's your answer is
4 "When did you first think of this	4 that you didn't do any experimental work towards
5 invention?"	5 carrying out the invention; correct?
6 Answer: "September 27, 2011."	6 A. That's correct, because it was a
7 Is that right?	7 computational algorithm.
8 A. That's correct.	8 Q. Right. The the invention is a
9 Q. And I guess I should ask two questions:	9 computational algorithm. It's not something that
10 That's what it says. And it's accurate; correct?	10 you do physically; correct?
11 A. That is what it says. And that is	11 A. It's not something that I I think
12 accurate.	12 the way I answered that question was it's not some
Q. Thank you. And it says (as read):	13 kind of a wet lab technique. It's a computational
"What record do you have to substantiate	14 algorithm.
15 this date?"	15 Q. And then you say, (as read):
Then it says (as read):	16 "When did you first make written
"This disclosure, email from Greg to Caleb	į
18 with photo of whiteboard outlining method."	18 Answer: "September 27, 2011."
19 You see that?	You see that there?
20 A. I do see that.	20 A. I do.
Q. And it says (as read):	Q. Now, on every page of this document you
"To whom did you first disclose this	22 and Doctor Kennedy have signed it and dated it
23 invention?"	23 November 7, 2011, other than the last page; is that
23 invention?" 24 And the answer is "Tom Meyers." 25 Who's that?	24 correct? 25 A. So there's a signature there are two

16 (Pages 58 - 61)



CONFIDENTIAL

	Page 326	
1 ATTACH TO DEPOSITION OF: GREGORY J. PORRECA, PhD CASE: INVITAE VS. NATERA		
2 ERRATA SHEET		
3		
INSTRUCTIONS: After reading the transcript of your 4 deposition, note any change or correction to your		
testimony and the reason therefor on this sheet. 5 DO NOT make any marks or notations on the		
transcript volume itself. Sign and date this		
6 errata sheet (before a Notary Public, if required). Refer to page 324 of the transcript for errata		
7 sheet distribution instructions.		
8 PAGE LINE CHANGE:		
9 REASON:		
CHANGE: 10 REASON:		
CHANGE: 11 REASON:		
CHANGE:		
12 REASON: CHANGE:		
13 REASON:		
CHANGE: 14 REASON:		
CHANGE:		
CHANGE:		
16 REASON: CHANGE:		
17 REASON:		
18 I have read the foregoing transcript of my deposition and except for any corrections or		
19 changes noted above, I hereby subscribe to the transcript as an accurate record of the statements		
20 made by me.		
21 GREGORY J. PORRECA, PhD		
22		
Subscribed and sworn to before me 23 this		
24 Notary Public		
25 My Commission Expires:		

EXHIBIT B

	Page 1
1	UNITED STATES DISTRICT COURT
2	FOR THE DISTRICT OF DELAWARE
3	*******
4	INVITAE CORPORATION,
5	Plaintiff,
	•
6	vs. Case No. 1:21-cv-01635-GBW
	Case No. 1:21-cv-00669-GBW
7	NATERA, INC.,
8	Defendant.
9	******
10	**HIGHLY CONFIDENTIAL - ATTORNEYS EYES ONLY**
11	REMOTE VIDEOTAPED DEPOSITION OF
12	DAN EDWARD KRANE, PH.D.
13	New York, New York
14	August 31, 2023
15	
16	
17	
18	
19	
20	
21	
22	Reported by:
23	KATHY S. KLEPFER, RMR, RPR, CRR, CLR
24	JOB NO. 6062706
25	

HIGHLY CONFIDENTIAL - ATTORNEYS EYES ONLY

1	Page 2	1	Page 4 INDEX
1	August 31, 2023		XAMINATION OF DAN E. KRANE, PH.D.: PAGE
2	8:30 a.m.		y Mr. Klein 8
3	REMOTE VIDEOTAPED deposition of DAN	4	•
4	EDWARD KRANE, PH.D., before Kathy S.	5	
5	Klepfer, a Registered Professional Reporter,		RANE EXHIBITS: PAGE
6	Registered Merit Reporter, Certified		exhibit 1, Expert Report of Dan E. Krane 5
7	Realtime Reporter, Certified Livenote		xhibit 2, Rebuttal Expert Report of Dan E. 5 frane to the Opening Expert Report of Michael
8	Reporter, and Notary Public of the State of		Metzker, Ph.D.
9	New York.		xhibit 3, Corrected Rebuttal Expert Report of 5
10			Oan E. Krane to the Opening Expert Report of
11		11 Is	stavan Albert, Ph.D.
12			xhibit 4, Reply Expert Report of Dan E. Krane, 5
13			h.D. to Rebuttal Expert Report of Istavan
14			lbert, Ph.D.
15 16		P	xhibit 5, Reply Expert Report of Dan E. Krane, 5 h.D. to Rebuttal Expert Report of Michael
17			Metzker, Ph.D. (xhibit 6, U.S. Patent 10,604,799 56
18			xhibit 6, U.S. Patent 10,604,799 56 xhibit 7, CigarUtils.java file 173
19			xhibit 8, U.S. Patent No. 11,155,863 223
20		19	, , , , , , , , , , , , , , , , , , , ,
21		20	
22		21	
23		22	
24		23 24	
25		25	
1 2	Page 3 APPEARANCES:	1 2	Page 5 (Krane Exhibit 1, Expert Report of Dan E. Krane, marked for identification as of
3	BLUE PEAK PARTNERS	3	this date.)
4	Attorneys for Plaintiff	4	(Krane Exhibit 2, Rebuttal Expert
5	3139 W. Holcombe Blvd.	5	Report of Dan E. Krane to the Opening Exper
6	PMB 8160	6	Report of Michael Metzker, Ph.D., marked for
7	Houston, TX 77025	7	identification as of this date.)
8	BY: JUSTIN CONSTANT, ESQ.	8	(Krane Exhibit 3, Corrected Rebuttal
9		9	Expert Report of Dan E. Krane to the Opening
10	GROOMBRIDGE WU BAUGHMAN & STONE, LLP	10	Expert Report of Istavan Albert, Ph.D.,
11	Attorneys for Defendant	11	marked for identification as of this date.)
12	565 Fifth Avenue	12	(Krane Exhibit 4, Reply Expert Report
13	New York, NY 10017	13	of Dan E. Krane, Ph.D. to Rebuttal Expert
14	BY: DANIEL KLEIN, ESQ.	14	Report of Istavan Albert, Ph.D., marked for
15	daniel.klein@groombridgewu.com	15	identification as of this date.)
16	ARIELLA BAREL, ESQ.	16	(Krane Exhibit 5, Reply Expert Report
17	ariella.barrel@groombridgewu.com	17	of Dan E. Krane, Ph.D. to Rebuttal Expert
18		18	Report of Michael Metzker, Ph.D., marked for
19		19	identification as of this date.)
20		20	THE VIDEOGRAPHER: Good morning.
21	ALSO PRESENT:	21	We're going on the video record at
22	JEFF MENTON, Videographer	22	approximately 8:35 a.m. on August 31, 2023.
23	CARISSA NARCISCO, Exhibit Tech.	23	Please note that this deposition is
1		24	being conducted virtually. Quality of
24 25		25	recording depends on the quality of camera

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	Page 6	Page 8
1	and internet connections of participants.	1 DAN EDWARD KRANE, called as a
2	What is seen from witness and heard	2 witness, having been duly sworn by a Notary
3	on-screen is what will be recorded.	3 Public, was examined and testified as
4	Audio and video recording will	4 follows:
5	continue to take place unless all parties	5 EXAMINATION BY
6	agree to go off the record.	6 MR. KLEIN:
7	This is video media disk 1 of the	7 Q. Well, Good morning.
8	video-recorded deposition of Daniel Krane,	8 Could you state and spell your name
9	taken by counsel for the defendant, in the	9 and provide your home address, please?
10	matter of Invitae Corporation versus Natera,	10 A. Yes. My name is Dan Edward Krane.
11	Inc. This case is filed in the United	11 And let me just note that that's I've been
12	States District Court, District of Delaware.	12 seeing "Daniel" show up on a few of the things
13	There are two case numbers: 21-669-GDW and	13 here. It's actually my legal name is Dan, and
14	21-1635-GDW.	14 that is spelled D-A-N, and the last name is
15	This deposition is being conducted	15 spelled K-R-A-N-E.
16	remotely using virtual technology. My name	My home address is 1102 Mead, M-E-A-D,
17	is Jeff Menton. I am the certified legal	17 Road, in Xenia, X-E-N-I-A, Ohio. The Zip Code
18	videographer. The court reporter is Kathy	18 is 45385.
19	Klepfer, and we are both from Veritext New	19 Q. Thank you. And I think I'll be able
20	York.	20 to get your name right. And also, you have
21	All counsel consent to this remote	21 great initials. We share in both.
22	video arrangement and waive any objections	22 So have you been deposed before?
23	to this manner of reporting.	23 A. I have not been deposed in a patent
24	If there are any objections to the	24 litigation situation before, but I have been
25	court reporter swearing in the witness	25 deposed in the context of criminal trials and,
25	court reporter swearing in the withess	23 deposed in the context of criminal trials and,
1	Page 7 remotely on this remote video arrangement,	Page 9 1 on occasion, in some civil trials involving DNA
2	please state them now.	_
$\frac{2}{3}$	Not hearing any objections, counsel	2 testing. 3 O. Were those federal or state court
	will now state their appearances and	
4	* *	4 proceedings in which you were deposed? 5 A. I believe both. I'm certain of
5	affiliations for the record, beginning with	
6	the noticing attorney, and then the court	6 federal. I'm pretty confident of state as well.
7	reporter will swear the witness in.	7 Q. How recently were you last deposed in
8	MR. KLEIN: Daniel Klein from	8 a case?
9	Groombridge Wu Baughman & Stone here on	·
10	behalf of defendant Natera, Inc., and with	10 blend together, but the one that comes most
11	me is my colleague Ariella Barel.	11 clearly to mind would have been about two and a
12	MR. CONSTANT: Justin Constant with	12 half years ago.
13	Blue Peak Law Group, representing Invitae.	13 Q. Okay. So I'll just go over some
14	* * *	14 basics which you probably know, but because the
15		15 official record of these proceedings is going to
16		16 be the transcript, I'll need verbal answers from
17		17 you as opposed to head nods or physical
18		18 gestures.
19		19 I will do my best not to speak over
20		20 you. I would appreciate you doing the same.
21		21 There may on occasion be an instance where I
22		22 accidentally cut you off. I will do my best not
23		23 to do that and give you time to finish your
24		24 answer.
25		25 If I ask you a question and you
		<u> </u>

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Page 258	Page 260
1 your rebuttal to Dr. Metzker.	1 Court, would you also agree that this Q score is
2 A. I see from my Table of Contents that	2 likewise a description of one reference of
3 there's some discussion about the description of	3 one sequence with reference to another sequence
4 CASAVA on page 22, but the specific response to	4 in a, albeit, literal and narrow form?
5 Dr. Metzker does begin later.	5 MR. CONSTANT: Objection. Form.
6 Would you like me to look first at	6 THE WITNESS: Counsel, just to in
7 page 170?	7 an effort to save us time and to give you a
8 Q. Yes, please.	8 thorough answer and very efficiently, let me
9 A. All right. I am at page 170.	9 just point you to what I say in paragraph
10 Q. Now, you understand that what the	10 715 and, you know, it begins "when Q scores
11 Dr. Metzker refers to that, in his opinion,	11 merely indicate probability."
12 shows a read-to-contig description is the Q	And if you want, we can look further
13 score, correct?	at what's there, but I think the answer to
14 A. I understand that he characterizes the	your question is what's in my report in 715.
15 Q score as a read-to-contig description.	So, in some very narrow literal sense, a Q
16 Q. And why don't you take a look at page	score is a descriptor, but it's not the kind
17 173 of your report.	of descriptor that will be useful for the
18 A. I'm at page 173.	application that's described in these
19 Q. Uh-huh. And you see you've got a	patents, that combination step.
20 call-out from the CASAVA manual there?	20 BY MR. KLEIN:
21 A. I see that.	21 Q. I understand.
22 Q. Right above paragraph 714?	But so, too, is a CIGAR string on its
23 A. Yes.	23 own, in your opinion, equally useful or not
24 Q. And it says, "The relative	24 useful, correct?
25 probabilities of these alignments for each read	25 MR. CONSTANT: Objection. Form.
I	
	3
Page 259	Page 261
Page 259 1 are used to call the indel's genotype and	Page 261 THE WITNESS: A CIGAR string is so
Page 259 1 are used to call the indel's genotype and 2 calculate the associated quality score."	Page 261 1 THE WITNESS: A CIGAR string is so 2 much more useful than the Q score, and yet,
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	Page 290		Page 292
1	Q. And that if I could direct you to	1	THE VIDEOGRAPHER: We're on the
2	page 141 of your opening report.	2	record.
3	A. Very helpful. Thank you.	3	MR. KLEIN: We are on the record.
4	Q. You're welcome.	4	MR. CONSTANT: Oh, we are? I
5	A. Yes, that is on point.	5	apologize.
6	Q. And the license that you were	6	Yes, so we reserve the right under
7	referring to is what's called the Archer-BD	7	Federal Rules of Civil Procedure 30(e) to
8	license agreement, correct?	8	give an errata, and that's it. No further
9	A. That is correct.	9	questions.
10	Q. And that license agreement involves	10	THE VIDEOGRAPHER: Would you like to
11	patents covering technology related to	11	give the court reporter any transcripts
12	stochastic labeling, correct?	12	orders?
13	A. Stochastic labeling is involved, yes.	13	MR. CONSTANT: No, I I don't need a
14	MR. KLEIN: Can we just go off the	14	transcript, and just the Weil default.
15	record for like two minutes?	15	THE VIDEOGRAPHER: All right. Ready
16	I'm sorry.	16	to go off?
17	THE VIDEOGRAPHER: Going off the video	17	MR. KLEIN: Yeah, we can go off the
18	record at 4:44 p.m.	18	record. I want to say something about the
19	(Recess.)	19	transcript order, but we don't need to be on
20	THE VIDEOGRAPHER: We're back on the	20	the record for that.
21	video record at 4:47 p.m.	21	THE VIDEOGRAPHER: Okay. This
22	Please proceed.	22	concludes today's testimony given by Dan
23	MR. CONSTANT: Sorry. Dan, how	23	Krane, Ph.D. The total number of media
24	much do you know how much time we have	24	disks was 7 and will be retained by Veritext
25	left?	25	New York. The time is 4:49 p.m., and we're
	Page 291		Page 293
1	MR. KLEIN: 14.	1	going off the video record.
2	MR. CONSTANT: Sorry. I just realized	2	(Whereupon, the deposition concluded
3	I had my speaker off. There we go.	3 4	at 4:49 p.m.) oOo
4	Can you say that one more time?	5	000
5	MR. KLEIN: 14 minutes.	6	
6	MR. CONSTANT: 14 minutes. All right.	7	
7	I got it. Sorry. I thought I was losing my	8	
8	mind.	9	
9	MR. KLEIN: No worries.	10	
10	MR. CONSTANT: I appreciate it.	11	DANE KDANE DUD
11	MR. KLEIN: Of course.	12	DAN E. KRANE, PH.D.
12	Dr. Krane, I have no further	12 13	Subscribed and sworn to
13	questions. I really appreciate your time		before me this day
14	today.	14	of 2023.
15	THE WITNESS: Well, Dan, it's been a	15	
16	long day, but I appreciate your good nature,		
17	and I'm glad that we've had a chance to	16	
18	talk. I hope that I've been able to be of	17	
19	some help to you.	18 19	
20	MR. KLEIN: Yeah. Thank you.	20	
21	MR. CONSTANT: Okay. Yeah, and if you	21	
22	don't mind, could we go back on the record	22	
23	for just one minute just so I can reserve	23	
1 2 4	the right to give an errata under 30(e)?	24	
24			
25	And that's it.	25	

		.
	GED TYPICA - TEL	Page 294
1	CERTIFICATE	
2	STATE OF NEW YORK)	
,	: SS	
3	COUNTY OF NEW YORK)	
4	I, Kathy S. Klepfer, a Registered	
5	Merit Reporter and Notary Public within and	
6	for the State of New York, do hereby	
7	certify:	
8	That DAN E. KRANE, PH.D., the witness	
9	whose deposition is herein before set forth,	
10	was duly sworn by me and that such	
11	deposition is a true record of the testimony	
12	given by such witness.	
13	I further certify that I am not	
14	related to any of the parties to this action	
15	by blood or marriage and that I am in no way	
16	interested in the outcome of this matter.	
17	In witness whereof, I have hereunto	
18	set my hand this 5th day of September 2023.	
19	11/-	
	Lety S. Klepfer	
20		
	KATHY S. KLEPFER, RPR, RMR, CR	RR, CLR
21		
22		
23		
24		
25		
		Page 206
1 N	AME OF CASE: Invitae v. Natera	Page 296
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EXHIBIT C

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

)
) Case No. 21-cv-669-GBW
) JURY TRIAL DEMANDED
) HIGHLY CONFIDENTIAL –
) ATTORNEYS EYES ONLY)
)))
) Case No. 21-cv-01635-GBW
) JURY TRIAL DEMANDED
) HIGHLY CONFIDENTIAL – ATTORNEYS EYES ONLY
) ATTORNETS ETES ONET
)

INVITAE CORPORATION'S SUPPLEMENTAL RESPONSES AND OBJECTIONS TO NATERA, INC.'S SECOND SET OF INTERROGATORIES (NO. 9)¹

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, the Local Rules of the United States District Court for the District of Delaware ("Local Rules"), the District of Delaware Default Standard for Discovery, including Discovery of Electronically Stored Information ("Default Standard"), and any other applicable Orders or rules, Plaintiff Invitae

¹ Invitae notes that Natera identified this Interrogatory as being Interrogatory No. 8. Prior to serving this Interrogatory, however, Natera had already served eight interrogatories. Accordingly, Invitae identifies this Interrogatory as Interrogatory No. 9.

Corporation ("Invitae") hereby makes the following supplemental responses and objections to Defendant Natera, Inc.'s ("Natera") Second Set Of Interrogatories (No. 9).

The failure of Invitae to make a specific objection to any particular aspect of Natera's Interrogatories is not, and should not be construed as, an admission that responsive documents or information exist. Any statement that Invitae will produce documents or information does not mean that any such documents or information exist.

GENERAL OBJECTIONS

- 1. The following responses, while based on a diligent investigation by Invitae and its counsel, are necessarily supported only by those facts and writings presently and specifically known and readily available. Discovery in this matter is ongoing. As this Action proceeds, further information and/or documents may be considered, or their significance better understood, and Invitae reserves the right to change, amend or supplement these responses. Invitae therefore makes these responses without prejudice to its right to produce at any stage of these proceedings, including at trial, evidence of any facts or information that Invitae may later recall or discover. Invitae further reserves the right to change, amend or supplement any or all of the matters contained in these responses with facts or information that it learns were omitted, including by inadvertence, mistake, or excusable neglect, and as additional facts are ascertained and contentions are made in this litigation. A partial response to any interrogatory that has been objected to in whole or in part is not a waiver of the objection. By asserting various objections, Invitae does not waive other objections that may become applicable.
- 2. These responses are made solely for the purposes of this Action, and are subject to all objections as to competence, authenticity, relevance, materiality, privilege, and admissibility. All such objections and grounds are expressly reserved and may be interposed at the time of trial

- 3. Each and all of Invitae's general objections are hereby expressly incorporated into each and all of Invitae's specific responses. For particular emphasis, one or more of these general objections may be reiterated in a specific response. The absence or inclusion or any reiteration in a specific response is neither intended as, nor shall be construed as, a limitation or waiver of any general objection or any other specific objection made herein.
- 4. No incidental or implied admissions are intended by the responses below. The fact that Invitae has answered or objected to all or part of an interrogatory should not be construed or taken as an admission that Invitae accepts or admits the existence of any purported facts set forth or assumed by such interrogatory or that Invitae has waived or intended to waive any part of any objection to the interrogatory.
- 5. Invitae objects to the interrogatories, including the definitions and instructions contained therein, to the extent that they call for information and/or documents protected by the attorney-client privilege, attorney work-product doctrine, or other applicable privileges or immunities. Invitae further objects to the interrogatories to the extent that they purport to seek or call for the information constituting, recording, or reflecting the work product of Invitae's attorneys, including their thoughts, opinions, or mental impressions in connection with the preparation, prosecution, avoidance or defense of any claim by or against Invitae. Invitae also objects to the interrogatories to the extent that they seek information protected by the right of privacy contained in the United States Constitution, or other applicable statute or case law. Nothing contained in these responses is intended as, nor shall in any way be deemed, a waiver of the attorney-client privilege, attorney work product doctrine, right of privacy or other applicable privilege or immunity. Invitae objects to logging privileged documents created on or after the date of the filling of the Complaint in this Action. Invitae does not waive, intentionally or

otherwise, any attorney-client privilege, work-product immunity, or any other privilege, immunity, or other protection that may be asserted to protect any information from disclosure.

- 6. Invitae objects to the interrogatories, including the definitions and instructions contained therein, to the extent that they prematurely seek expert discovery.
- 7. Invitae objects to the interrogatories, including the definitions and instructions contained therein, to the extent that they seek discovery of confidential and/or competitive information, including, for example, trade secrets or other confidential research, development or commercial information. Invitae will only produce such information in accordance with the protective order to be entered in this Action, including special safeguards regarding the handling of and access to highly confidential or competitive information.
- 8. Invitae objects to the interrogatories, including the definitions and instructions contained therein, to the extent that they call for information and/or documents that Invitae may not produce without the consent of third parties. To the extent the consent of any third party is necessary to produce any such information and/or documents, Invitae will not produce such information and/or documents until it has received such consent.
- 9. Invitae objects to the interrogatories, including the definitions and instructions contained therein, to the extent that they call for information and/or documents that are not relevant to any claim or defense in this Action and/or that are not proportional to the needs of the case.
- 10. Invitae objects to the interrogatories, including the definitions and instructions contained therein, to the extent that they purport to require Invitae to search for or produce information and/or documents that are not within its possession, custody or control. Invitae will use reasonable diligence to locate information and/or documents within its possession, custody, or control.

- 11. Invitae objects to the interrogatories, including the definitions and instructions contained therein, to the extent that (i) the discovery sought by any such interrogatory is unreasonably cumulative, duplicative, obtainable form other sources that are more convenient, less burdensome or less expensive, the information is as easily ascertainable to the Natera as it is to Invitae, or is readily available from public sources, and/or (ii) compliance with any such interrogatory would be unduly burdensome, expensive, harassing and/or oppressive.
- 12. Invitae objects to the interrogatories, including the definitions and instructions contained therein, as overly broad and unduly burdensome to the extent that they fail to specify an appropriate time period, thereby seeking information and/or documents that are not relevant to any claim or defense in this Action and/or that are not proportional to the needs of the case.
- 13. Invitae objects to the interrogatories, including the definitions and instructions contained therein, to the extent that they call for legal conclusions.
- 14. Invitae objects to the interrogatories, including the definitions and instructions contained therein, to the extent that they are vague and ambiguous.
- 15. Invitae objects to the definition of "Invitae," "you", and "your" as being overbroad, unduly burdensome, and oppressive, to the extent that it purports to impose duties beyond those imposed by the Federal Rules of Civil Procedure, the Local Rules, or any order or ruling by the Court in this action, including by seeking information and/or documents that are not relevant to any claim or defense to the needs of the case. Invitae also objects to this definition to the extent it renders any part of any interrogatory unduly burdensome, harassing, oppressive, or overbroad to the extent it purports to include entities other than Invitae. For purposes of its responses, Invitae will construe these terms to mean only Invitae, and will produce documents and/or information only to the extent they are in possession, custody, or control of Invitae.

- 16. Invitae objects to Natera's definitions of "document," "communication," "regarding," "identify or identifying," and "identify all facts" as being overly broad, unduly burdensome and oppressive, calling for information protected by the attorney-client privilege or work product doctrine, outside the scope of discovery, and as seeking information and documents beyond Invitae's possession, custody, or control.
- 17. Invitae objects to each Interrogatory to the extent it seeks production of "all," and "each," document that refers or relates to a particular subject on the grounds of overbreadth, undue burden and expense, and that it calls for information outside the scope of discovery.
- 18. Invitae objects to each Interrogatory to the extent a response is sought with respect to a question of law or to the extent a response calls for an expert opinion.
- 19. Invitae also objects to each Instruction as unduly burdensome, harassing, oppressive and overbroad to the extent it is inconsistent with or calls for discovery beyond the scope of the Federal Rules of Civil Procedure, the Local Rules for the District of Delaware, or any order or ruling of this or any other Court, including by seeking information and/or documents that are not relevant to any claim or defense in this Action and/or that are not proportional to the needs of the case. Invitae will comply with the requirements of the Federal Rules of Civil procedure, the Local Rules, and any order or ruling by the Court in this Action in responding to the interrogatories.
- 20. Invitae objects to each Interrogatory to the extent it seeks information already in Natera's possession or is available to Natera from public sources for which the burden of obtaining such information is the same or less for Natera as it is for Invitae. Invitae provides these responses with the understanding that Invitae is in possession of or has access to such sources, including, without limitation, Invitae's website.

- 21. Invitae's agreement to produce any category of information or documents is not a representation that any such information or documents in that category actually exist in Invitae's possession, custody, or control, or can be located through a reasonable search, or that such documents are relevant.
- 22. Subject to and without waiving these general Objections, Invitae responds and specifically objects to Natera's interrogatories as follows:

INTERROGATORY NO. 9:

Describe in full and informative detail all facts, evidence, and arguments that Plaintiff contends rebut the arguments in Natera's Initial Invalidity Contentions that the Asserted Claims are invalid, including the level of education, training, specialty, and experience that Plaintiff contends a person having ordinary skill in the art for the subject matter described and claimed in the Asserted Patents would have had as of the date of the claimed invention(s). Your response should identify each of the alleged differences between the inventions claimed in the Asserted Patents and the prior art, any alleged lack of motivation to combine, and any alleged lack of reasonable expectation of success. It should also identify all documents and information supporting or contradicting such contentions, and the natural persons most knowledgeable of such contentions and documents.

RESPONSE TO INTERROGATORY NO. 9 (2022-06-21):

Invitae incorporates each and all of its General Statements and Objections as if set forth fully herein. Invitae further objects to this interrogatory as a contention interrogatory that prematurely seeks expert discovery. Invitae will provide its validity positions in one or more expert reports served in accordance with the schedule set by the Court and incorporates those reports by reference into this response. Invitae further objects to this interrogatory as vague, ambiguous, unduly burdensome, overbroad, harassing, and oppressive. Invitae further objects to this interrogatory to the extent it calls for a legal conclusion. Invitae further objects to this interrogatory to the extent it is compound and contains subparts in violation of Rule 33 of the Federal Rules of Civil Procedure. Invitae further objects to this interrogatory to the extent it calls for information protected from discovery under the attorney-client privilege, the attorney work-product doctrine,

or any other applicable privilege or immunity. Invitae further objects to this interrogatory to the extent it seeks information concerning patent claims and claim terms. Invitae further objects to this interrogatory to the extent it improperly attempts to shift the burden of proof to Invitae with respect to validity.

Subject to its general and specific objections, and based on its investigation to date, Invitae responds as follows:

On March 31, 2020, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 10,604,799 ("'799 Patent"). On October 19, 2021, the United States Patent and Trademark Office duly and legally reissued U.S. Patent No. 11,149,308 ("'308 Patent"). On October 26, 2021, the United States Patent and Trademark Office duly and legally issued U.S. Patent No. 11,155,863 ("'863 Patent"). Under 35 U.S.C. § 282(a), a "patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim."

Regarding Natera's allegations of anticipation as stated in its Claim Charts, Appendices 1-12, Invitae responds as follows:

• Appendix 1: The cited prior art in this Claim Chart does not anticipate any of the Asserted Claims because it fails to specifically disclose, teach, or embody the unique combination of steps involved in the Asserted Patents' sequence assembly approach, specifically the assembly approach in which sequencing reads are grouped into contigs and aligned to a reference genome, the original individual reads are re-aligned to the contigs, and then the two are combined, improving upon then-current DNA sequencing technology. For example, Natera is unable to cite a single passage referring to "contigs"

in support of its allegations that claim elements 1[e] and [g] of the '799 Patent were disclosed and/or rendered obvious in the prior art. Nor does Natera's cited prior art disclose the similar claim elements the '308 and '863 Patents.

- Appendix 2: The cited prior art in this Claim Chart does not anticipate any of the Asserted Claims because it fails to specifically disclose, teach, or embody the unique combination of steps involved in the Asserted Patents' sequence assembly approach, specifically the assembly approach in which sequencing reads are grouped into contigs and aligned to a reference genome, the original individual reads are re-aligned to the contigs, and then the two are combined, improving upon then-current DNA sequencing technology. For example, Natera's citations in support of its allegations that claim element 1[g] of the '799 Patent was disclosed and/or rendered obvious in the prior art merely recite experimental results, failing to mention any form of combination of descriptions even once. The prior art cited in Appendix 2, to the extent it generates contigs at all, does not align reads to the contigs, but realigns reads to the reference. Nor does Natera's cited prior art disclose the similar claim elements in the '308 and '863 Patents.
- Asserted Claims because it fails to specifically disclose, teach, or embody the unique combination of steps involved in the Asserted Patents' sequence assembly approach, specifically the assembly approach in which sequencing reads are grouped into contigs and aligned to a reference genome, the original individual reads are re-aligned to the contigs, and then the two are combined, improving upon then-current DNA sequencing technology. For example, Natera's citations in support of its allegations that claim

element 1[g] of the '799 Patent was disclosed and/or rendered obvious in the prior art in fact describe an entirely different process, one that only functions once indels have been identified. Nor does Natera's cited prior art disclose the similar claim elements in the '308 and '863 Patents.

- Appendix 4: The cited prior art in this Claim Chart does not anticipate any of the Asserted Claims because it fails to specifically disclose, teach, or embody the unique combination of steps involved in the Asserted Patents' sequence assembly approach, specifically the assembly approach in which sequencing reads are grouped into contigs and aligned to a reference genome, the original individual reads are re-aligned to the contigs, and then the two are combined, improving upon then-current DNA sequencing technology. For example, Natera's citations in support of its allegations that claim element 1[g] of the '799 Patent was disclosed and/or rendered obvious in the prior art in actuality merely recites an ordinary contig-based assembly process. The cited prior art merely teaches an improved technique for generating contigs. Nor does Natera's cited prior art disclose the similar claim elements in the '308 and '863 Patents.
- Appendix 5: The cited prior art in this Claim Chart does not anticipate any of the Asserted Claims because it fails to specifically disclose, teach, or embody the unique combination of steps involved in the Asserted Patents' sequence assembly approach, specifically the assembly approach in which sequencing reads are grouped into contigs and aligned to a reference genome, the original individual reads are re-aligned to the contigs, and then the two are combined, improving upon then-current DNA sequencing technology. For example, Natera fails to provide a single citation that even mentions contigs in support of its allegations that claim element 1[d] of the '799 Patent was

disclosed and/or rendered obvious in the prior art. Nor does Natera's cited prior art disclose the similar claim element in the '308 and '863 Patents. The cited prior art in Appendix 6 fails to disclose alignment of reads to contigs followed by combining reference alignments and sequence read alignments.

- Appendix 6: The cited prior art in this Claim Chart does not anticipate any of the Asserted Claims because it fails to specifically disclose, teach, or embody the unique combination of steps involved in the Asserted Patents' sequence assembly approach, specifically the assembly approach in which sequencing reads are grouped into contigs and aligned to a reference genome, the original individual reads are re-aligned to the contigs, and then the two are combined, improving upon then-current DNA sequencing technology. For example, Natera's citations in support of its allegations that claim element 1[g] of the '799 Patent was disclosed and/or rendered obvious in the prior art in actuality merely recites an ordinary contig-based assembly process. Nor does Natera's cited prior art disclose the similar claim elements in the '308 and '863 Patents.
- Appendix 7: The cited prior art in this Claim Chart does not anticipate any of the Asserted Claims because it fails to specifically disclose, teach, or embody the unique combination of steps involved in the Asserted Patents' sequence assembly approach, specifically the assembly approach in which sequencing reads are grouped into contigs and aligned to a reference genome, the original individual reads are re-aligned to the contigs, and then the two are combined, improving upon then-current DNA sequencing technology. For example, Natera's citations in support of its allegations that claim element 1[g] of the '799 Patent was disclosed and/or rendered obvious in the prior art in actuality merely recites an ordinary contig-based assembly process. Even to the

extent Natera contends the cited prior art discloses alignment reads to contigs and alignment of contigs to a reference, those processes are not used as part of an integrated process. Nor does Natera's cited prior art disclose the similar claim elements in the '308 and '863 Patents.

- Asserted Claims because it fails to specifically disclose, teach, or embody the unique combination of steps involved in the Asserted Patents' sequence assembly approach, specifically the assembly approach in which sequencing reads are grouped into contigs and aligned to a reference genome, the original individual reads are re-aligned to the contigs, and then the two are combined, improving upon then-current DNA sequencing technology. For example, Natera's citations in support of its allegations that claim element 1[g] of the '799 Patent was disclosed and/or rendered obvious in the prior art in actuality merely recites an ordinary contig-based assembly process. Even to the extent Natera contends the cited prior art discloses alignment reads to contigs and alignment of contigs to a reference, those processes are not used as part of an integrated process. Nor does Natera's cited prior art disclose the similar claim elements in the '308 and '863 Patents.
- Appendix 9: The cited prior art in this Claim Chart does not anticipate any of the Asserted Claims because it fails to specifically disclose, teach, or embody the unique combination of steps involved in the Asserted Patents' sequence assembly approach, specifically the assembly approach in which sequencing reads are grouped into contigs and aligned to a reference genome, the original individual reads are re-aligned to the contigs, and then the two are combined, improving upon then-current DNA sequencing

technology. For example, Natera's citations in support of its allegations that claim element 1[g] of the '799 Patent was disclosed and/or rendered obvious in the prior art in actuality merely recites an ordinary contig-based assembly process. The cited prior art does not disclose alignment of contigs to a reference. Nor does Natera's cited prior art disclose the similar claim elements in the '308 and '863 Patents.

- Appendix 10: The cited prior art in this Claim Chart does not anticipate any of the Asserted Claims because it fails to specifically disclose, teach, or embody the unique combination of steps involved in the Asserted Patents' sequence assembly approach, specifically the assembly approach in which sequencing reads are grouped into contigs and aligned to a reference genome, the original individual reads are re-aligned to the contigs, and then the two are combined, improving upon then-current DNA sequencing technology. For example, Natera's citations in support of its allegations that claim element 1[g] of the '799 Patent was disclosed and/or rendered obvious in the prior art in actuality merely recites an ordinary contig-based assembly process. The cited prior art does not disclose alignment of reads to contigs. Nor does Natera's cited prior art disclose the similar claim elements in the '308 and '863 Patents.
- Appendix 11: The cited prior art in this Claim Chart does not anticipate any of the Asserted Claims because it fails to specifically disclose, teach, or embody the unique combination of steps involved in the Asserted Patents' sequence assembly approach, specifically the assembly approach in which sequencing reads are grouped into contigs and aligned to a reference genome, the original individual reads are re-aligned to the contigs, and then the two are combined, improving upon then-current DNA sequencing technology. For example, Natera's very first citation in support of its allegations that

the '799 Patent was disclosed and/or rendered obvious in the prior art in fact describes an entirely different assembly process, one that does not use a reference sequence. Nor does Natera's cited prior art disclose the similar claim elements in the '308 and '863 Patents.

• Appendix 12: The cited prior art in this Claim Chart does not anticipate any of the Asserted Claims because it fails to specifically disclose, teach, or embody the unique combination of steps involved in the Asserted Patents' sequence assembly approach, specifically the assembly approach in which sequencing reads are grouped into contigs and aligned to a reference genome, the original individual reads are re-aligned to the contigs, and then the two are combined, improving upon then-current DNA sequencing technology. For example, Natera's citations in support of its allegations that claim element 1[g] of the '799 Patent was disclosed and/or rendered obvious in the prior art in actuality merely recites an ordinary contig-based assembly process. Nor does Natera's cited prior art disclose the similar claim elements in the '308 and '863 Patents.

Regarding Natera's allegations of obviousness, Natera has cited an excessive and unreasonable number of references as support, claiming that they render the Asserted Claims obvious "alone and/or in combination." This gives rise to an excessive and unreasonable number of potential combinations, rendering Natera's claims of obviousness entirely lacking in specificity. Should Natera narrow its allegations of obviousness to a more specific degree, Invitae will respond accordingly.

Regarding Natera's allegation that references from the time of the invention of the patent in similar and related fields disclosed relevant teachings reflecting motivations to combine, Natera has failed entirely to demonstrate this. At no point in any of Natera's Claim Charts, which it

describes as citing and presenting teachings reflecting motivations to combine, is a teaching reflecting motivation to combine actually found. In fact, at least some of Natera's cited prior art actually teaches away, such as in Appendix 11, where a method of sequence assembly without the use of a reference genome is described as a great achievement. Moreover, Natera's argument that there was a motivation to combine prior art is stated generically, without taking into account the individual features of the individual prior art references. To the extent Natera states its prior art and proposed motivations to combine more with more specificity, Invitae will respond accordingly.

Regarding Natera's allegation that skilled artisans were supposedly motivated and had a reasonable expectation of success to use the claimed method of sequence assembly, Natera has also failed to demonstrate this. Again, if skilled artisans truly had a reasonable expectation of success, Natera would not have been limited to prior art such as that which it cites in Appendix 11, which plainly teaches a method of sequence assembly entirely divorced from that which is claimed in the Asserted Patents. Moreover, Natera's argument that there was a reasonable expectation of successfully combining the prior art to achieve the claimed invention is stated generically, without taking into account the individual features of the individual prior art references. To the extent Natera states its prior art and bases for reasonable expectation of success with more specificity, Invitae will respond accordingly.

FIRST SUPPLEMENTAL RESPONSE TO INTERROGATORY NO. 9 (2023-04-28):

Invitae incorporates by reference its prior responses to this Interrogatory. Subject to its general and specific objections, and based on its investigation to date, Invitae further responds as follows:

The Asserted Patents are presumed valid pursuant to Pursuant to 35 U.S.C. § 282. Natera has not met its burden in showing with clear and convincing evidence that any prior art, alone or in combination, invalidates pursuant to 35 U.S.C. §§ 102 and/or 103, any Asserted Claim of the Asserted Patents. To the extent the alleged prior art is mentioned, described, or discussed by the Asserted Patents and/or known and considered by the PTO, the Asserted Patents were granted and are presumed valid over the prior art.

Regarding Natera's allegations of obviousness, Natera has cited an excessive and unreasonable number of references as support, claiming that they render the Asserted Claims obvious alone and/or in combination. This gives rise to an excessive and unreasonable number of potential combinations, rendering Natera's claims of obviousness entirely lacking in specificity. Further, Natera has not provided contentions explaining how the quoted text from the prior art references discloses a claim limitation. Natera also relies on the same disclosure of the same reference for different limitations in the same claim without explanation. Natera has also failed to provide contentions explaining why disclosures from one prior art reference would be combinable with different embodiments from the same reference or with disclosures from any other prior art reference(s) on a limitation-by-limitation basis.

To the extent that Natera demonstrates each of the claim elements was independently known in the prior art, Natera has failed to demonstrate obviousness because it has not identified any specific and sufficient basis to modify or combine known elements in each reference with a different element in another reference, with a reasonable expectation of success, to achieve the claimed invention. Natera's contentions rely upon after-the-fact reasoning and read the teachings of the invention at issue into the prior art and thus fail to overcome hindsight biases.

Natera's attempt to place prior art references in various categories and to combine one category with another fails to show a motivation to modify or combine individual references. Most of these references are not explained or relied upon in Natera's invalidity contentions. Natera fails to show that one of ordinary skill in the art would consider modifying such references or would have any expectation of success in doing so. For example, Natera has also failed to identify motivations to modify references or whether the references themselves function in a manner sufficient to accomplish their objectives and thus do not require modification. As another example, Natera has failed to show that references within each category are in the same or analogous field such that one of ordinary skill in the art would be motivated to look to the teachings of a given reference when considering another reference.

Appendix 1 – NextGENe

Natera has not met its burden in showing that the NextGENe software and associated references invalidate any Asserted Claims of the Asserted Patents. NextGENe, as disclosed in Natera's contentions, does not render any claim of the Asserted Patents invalid because, for example, the references do not disclose, teach, or render obvious alone or in combination with other prior art at least the following:

- a method for accurately identifying differences between a reference human genome and sequence reads obtained from a biological sample
- a method for assembling and aligning a plurality of sequence reads having mutations of different types
- inputting a reference genome and said plurality of sequence reads into a computer system comprising a processor coupled to a non-transitory memory; or performing genotyping by one or more computer software programs executing on at least one computer processor coupled to a computer-readable memory to perform a number of steps; or inputting a reference genome and the plurality of sequence reads into a computer system comprising a non-transitory memory and a processor coupled to the non-transitory memory, wherein the non-transitory memory has instructions stored thereon that, when executed by the processor, cause the processor to perform a number of steps

- assembling a contig from at least some of the plurality of sequence reads; or assembling a contig using the at least some of the sequence reads, the contig including information about positions of the at least some of the sequence reads relative to each other or to a reference
- identifying a plurality of contig:reference descriptions of mutations by aligning the contig to said reference genome; or aligning the contig to the reference human genome to obtain a reference alignment and storing the reference alignment in the computer-readable memory, the reference alignment indicative of first differences between the contig and the reference human genome; or identifying a plurality of contig-to-reference descriptions of the mutations by aligning the contig to a sequence of the reference genome
- identifying a plurality of read:contig descriptions by aligning each of the plurality of sequence reads to the contig; or aligning the at least some of the sequence reads to the contig to obtain sequence read alignments and storing the sequence read alignments in the computer-readable memory, the sequence read alignments indicative of second differences between the at least some of the sequence reads and the contig; or identifying a plurality of read-to-contig descriptions by aligning each of the at least some of the plurality of sequence reads to the contig
- combining the contig:reference descriptions with the read:contig descriptions to produce read:reference descriptions to map positional information of mutations found in the individual reads relative to the reference
- generating a read-to-reference description by aligning at least one of the plurality of contigto-reference descriptions with a corresponding at least one of the plurality of read-to-contig descriptions, wherein the read-to-reference description maps positional information of the mutations found in at least one of the at least some of the plurality of sequence reads relative to the sequence of the reference genome
- genotyping at least some of the sequence reads using a multi-stage alignment
- genotyping the at least some of the sequence reads by identifying multiple mutations in the
 at least some of the sequence reads based on the first differences and the second differences,
 the genotyping comprising mapping the at least some of the sequence reads to the reference
 genome by combining the reference alignment and the sequence read alignments to
 determine an identity of each of the multiple mutations and its location in the human
 reference genome
- assigning the reads to subsets based on the barcode sequences
- assigning the reads to subsets based on the barcode sequences and creating a unique contig
 for that subset
- creating the contig by overlapping consensus assembly; or assembling the contig comprises overlap consensus assembly
- creating the contig by searching a prefix tree for overlap between the reads; or assembling the contig by searching a prefix tree for overlap between the contig and the sequence of the reference genome

- sequencing the template nucleic acid by fragmenting the template nucleic acid, attaching the fragments to a surface of channels in a flow cell, and amplifying the attached fragments to create clusters, each cluster comprising a plurality of copies of the same template in one of the channels of the flow cell
- identifying a mutation based on the alignments to the contig and the reference sequence
- identifying a plurality of mutations
- identifying a plurality of mutations, wherein a first mutation is within about 100 nucleotides of a second mutation
- identifying a plurality of mutations, wherein the first mutation is a substitution and the second mutation is a deletion
- identifying a plurality of mutations, wherein the mutation is a deletion at the end of a sequence read
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 100 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 10 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 5 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel are proximal to one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel occurs at an end of a sequence read among the at least some of the sequence reads
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel has a length exceeding a length of one or more of the sequence reads
- aligning the contig to a reference sequence by using a first set of alignment parameters
- aligning each of the plurality of sequence reads to the contig by using a second set of alignment parameters
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome

- aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome and aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig, wherein the first gap penalty is greater than the second gap penalty
- aligning the contig to a reference sequence by using a first set of alignment parameters and
 aligning each of the plurality of sequence reads to the contig by using a second set of
 alignment parameters, wherein the first set of alignment parameters includes a first gap
 penalty and a first substitution penalty; the second set of alignment parameters includes a
 second gap penalty and a second substitution penalty; and the first gap penalty>the second
 gap penalty
- the sequence reads include sequence reads less than 150 bases in length
- the sequence reads comprise at least one million sequence reads
- storing the reference alignment in the computer readable memory by generating a first compact idiosyncratic gaped element report (CIGAR) string representing the reference alignment and storing the first CIGAR string in a Binary Alignment Map (BAM) format or a sequence alignment map (SAM) format in the computer readable memory
- storing the sequence read alignments in the computer-readable memory by generating second CIGAR strings representing the sequence read alignments and storing the second CIGAR strings in the BAM format or the SAM format in the computer readable memory
- storing results of genotyping the at least some of the sequence reads by generating a
 plurality of CIGAR strings and storing the plurality of CIGAR strings the computerreadable memory
- the reference genome is a human genome
- the instructions further cause the processor to create a file or variable containing a description of the mutations
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the file or variable is a binary alignment map (BAM) file comprising a Compact Idiosyncratic Gapped Alignment Report (CIGAR) string
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the description of the mutations comprises variant and positional information

Appendix 2 – GATK

Natera has not met its burden in showing that the GATK toolkit and associated references invalidate any Asserted Claims of the Asserted Patents. GATK, as disclosed in Natera's contentions, does not render any claim of the Asserted Patents invalid because, for example, the

references do not disclose, teach, or render obvious alone or in combination with other prior art at least the following:

- a method for assembling sequence reads
- a method for accurately identifying differences between a reference human genome and sequence reads obtained from a biological sample
- a method for assembling and aligning a plurality of sequence reads having mutations of different types
- inputting a reference genome and said plurality of sequence reads into a computer system comprising a processor coupled to a non-transitory memory; or performing genotyping by one or more computer software programs executing on at least one computer processor coupled to a computer-readable memory to perform a number of steps; or inputting a reference genome and the plurality of sequence reads into a computer system comprising a non-transitory memory and a processor coupled to the non-transitory memory, wherein the non-transitory memory has instructions stored thereon that, when executed by the processor, cause the processor to perform a number of steps
- assembling a contig from at least some of the plurality of sequence reads; or assembling a contig using the at least some of the sequence reads, the contig including information about positions of the at least some of the sequence reads relative to each other or to a reference
- identifying a plurality of contig:reference descriptions of mutations by aligning the contig to said reference genome; or aligning the contig to the reference human genome to obtain a reference alignment and storing the reference alignment in the computer-readable memory, the reference alignment indicative of first differences between the contig and the reference human genome; or identifying a plurality of contig-to-reference descriptions of the mutations by aligning the contig to a sequence of the reference genome
- identifying a plurality of read:contig descriptions by aligning each of the plurality of sequence reads to the contig; or aligning the at least some of the sequence reads to the contig to obtain sequence read alignments and storing the sequence read alignments in the computer-readable memory, the sequence read alignments indicative of second differences between the at least some of the sequence reads and the contig; or identifying a plurality of read-to-contig descriptions by aligning each of the at least some of the plurality of sequence reads to the contig
- combining the contig:reference descriptions with the read:contig descriptions to produce read:reference descriptions to map positional information of mutations found in the individual reads relative to the reference
- generating a read-to-reference description by aligning at least one of the plurality of contigto-reference descriptions with a corresponding at least one of the plurality of read-to-contig descriptions, wherein the read-to-reference description maps positional information of the mutations found in at least one of the at least some of the plurality of sequence reads relative to the sequence of the reference genome

- genotyping at least some of the sequence reads using a multi-stage alignment
- genotyping the at least some of the sequence reads by identifying multiple mutations in the at least some of the sequence reads based on the first differences and the second differences, the genotyping comprising mapping the at least some of the sequence reads to the reference genome by combining the reference alignment and the sequence read alignments to determine an identity of each of the multiple mutations and its location in the human reference genome
- attaching barcode sequences to the template nucleic acid
- assigning the reads to subsets based on the barcode sequences
- assigning the reads to subsets based on the barcode sequences and creating a unique contig
 for that subset
- creating the contig by overlapping consensus assembly; or assembling the contig comprises overlap consensus assembly
- creating the contig by searching a prefix tree for overlap between the reads; or assembling the contig by searching a prefix tree for overlap between the contig and the sequence of the reference genome
- sequencing the template nucleic acid by fragmenting the template nucleic acid, attaching the fragments to a surface of channels in a flow cell, and amplifying the attached fragments to create clusters, each cluster comprising a plurality of copies of the same template in one of the channels of the flow cell
- identifying a mutation based on the alignments to the contig and the reference sequence
- identifying a plurality of mutations
- identifying a plurality of mutations, wherein a first mutation is within about 100 nucleotides of a second mutation
- identifying a plurality of mutations, wherein the first mutation is a substitution and the second mutation is a deletion
- identifying a plurality of mutations, wherein the mutation is a deletion at the end of a sequence read
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 100 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 10 bases of one another

- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 5 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel are proximal to one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel occurs at an end of a sequence read among the at least some of the sequence reads
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel has a length exceeding a length of one or more of the sequence reads
- aligning the contig to a reference sequence by using a first set of alignment parameters
- aligning each of the plurality of sequence reads to the contig by using a second set of alignment parameters
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome
- aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome and aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig, wherein the first gap penalty is greater than the second gap penalty
- aligning the contig to a reference sequence by using a first set of alignment parameters and
 aligning each of the plurality of sequence reads to the contig by using a second set of
 alignment parameters, wherein the first set of alignment parameters includes a first gap
 penalty and a first substitution penalty; the second set of alignment parameters includes a
 second gap penalty and a second substitution penalty; and the first gap penalty>the second
 gap penalty
- the sequence reads include sequence reads less than 150 bases in length
- the sequence reads comprise at least one million sequence reads
- storing the reference alignment in the computer readable memory by generating a first compact idiosyncratic gaped element report (CIGAR) string representing the reference alignment and storing the first CIGAR string in a Binary Alignment Map (BAM) format or a sequence alignment map (SAM) format in the computer readable memory
- storing the sequence read alignments in the computer-readable memory by generating second CIGAR strings representing the sequence read alignments and storing the second CIGAR strings in the BAM format or the SAM format in the computer readable memory

- storing results of genotyping the at least some of the sequence reads by generating a
 plurality of CIGAR strings and storing the plurality of CIGAR strings the computerreadable memory
- the reference genome is a human genome
- the instructions further cause the processor to create a file or variable containing a description of the mutations
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the file or variable is a binary alignment map (BAM) file comprising a Compact Idiosyncratic Gapped Alignment Report (CIGAR) string
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the description of the mutations comprises variant and positional information

Appendix 3 – CASAVA

Natera has not met its burden in showing that the CASAVA software and associated references invalidate any Asserted Claims of the Asserted Patents. CASAVA, as disclosed in Natera's contentions, does not render any claim of the Asserted Patents invalid because, for example, the references do not disclose, teach, or render obvious alone or in combination with other prior art at least the following:

- a method for assembling sequence reads
- a method for accurately identifying differences between a reference human genome and sequence reads obtained from a biological sample
- a method for assembling and aligning a plurality of sequence reads having mutations of different types
- inputting a reference genome and said plurality of sequence reads into a computer system comprising a processor coupled to a non-transitory memory; or performing genotyping by one or more computer software programs executing on at least one computer processor coupled to a computer-readable memory to perform a number of steps; or inputting a reference genome and the plurality of sequence reads into a computer system comprising a non-transitory memory and a processor coupled to the non-transitory memory, wherein the non-transitory memory has instructions stored thereon that, when executed by the processor, cause the processor to perform a number of steps
- assembling a contig from at least some of the plurality of sequence reads; or assembling a contig using the at least some of the sequence reads, the contig including information about positions of the at least some of the sequence reads relative to each other or to a reference

- identifying a plurality of contig:reference descriptions of mutations by aligning the contig to said reference genome; or aligning the contig to the reference human genome to obtain a reference alignment and storing the reference alignment in the computer-readable memory, the reference alignment indicative of first differences between the contig and the reference human genome; or identifying a plurality of contig-to-reference descriptions of the mutations by aligning the contig to a sequence of the reference genome
- identifying a plurality of read:contig descriptions by aligning each of the plurality of sequence reads to the contig; or aligning the at least some of the sequence reads to the contig to obtain sequence read alignments and storing the sequence read alignments in the computer-readable memory, the sequence read alignments indicative of second differences between the at least some of the sequence reads and the contig; or identifying a plurality of read-to-contig descriptions by aligning each of the at least some of the plurality of sequence reads to the contig
- combining the contig:reference descriptions with the read:contig descriptions to produce read:reference descriptions to map positional information of mutations found in the individual reads relative to the reference
- generating a read-to-reference description by aligning at least one of the plurality of contigto-reference descriptions with a corresponding at least one of the plurality of read-to-contig descriptions, wherein the read-to-reference description maps positional information of the mutations found in at least one of the at least some of the plurality of sequence reads relative to the sequence of the reference genome
- genotyping at least some of the sequence reads using a multi-stage alignment
- genotyping the at least some of the sequence reads by identifying multiple mutations in the at least some of the sequence reads based on the first differences and the second differences, the genotyping comprising mapping the at least some of the sequence reads to the reference genome by combining the reference alignment and the sequence read alignments to determine an identity of each of the multiple mutations and its location in the human reference genome
- attaching barcode sequences to the template nucleic acid
- assigning the reads to subsets based on the barcode sequences
- assigning the reads to subsets based on the barcode sequences and creating a unique contig for that subset
- creating the contig by overlapping consensus assembly; or assembling the contig comprises overlap consensus assembly
- creating the contig by searching a prefix tree for overlap between the reads; or assembling the contig by searching a prefix tree for overlap between the contig and the sequence of the reference genome
- sequencing the template nucleic acid by fragmenting the template nucleic acid, attaching the fragments to a surface of channels in a flow cell, and amplifying the attached fragments

to create clusters, each cluster comprising a plurality of copies of the same template in one of the channels of the flow cell

- identifying a mutation based on the alignments to the contig and the reference sequence
- identifying a plurality of mutations
- identifying a plurality of mutations, wherein a first mutation is within about 100 nucleotides of a second mutation
- identifying a plurality of mutations, wherein the first mutation is a substitution and the second mutation is a deletion
- identifying a plurality of mutations, wherein the mutation is a deletion at the end of a sequence read
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 100 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 10 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 5 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel are proximal to one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel occurs at an end of a sequence read among the at least some of the sequence reads
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel has a length exceeding a length of one or more of the sequence reads
- aligning the contig to a reference sequence by using a first set of alignment parameters
- aligning each of the plurality of sequence reads to the contig by using a second set of alignment parameters
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome
- aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig

- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome and aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig, wherein the first gap penalty is greater than the second gap penalty
- aligning the contig to a reference sequence by using a first set of alignment parameters and
 aligning each of the plurality of sequence reads to the contig by using a second set of
 alignment parameters, wherein the first set of alignment parameters includes a first gap
 penalty and a first substitution penalty; the second set of alignment parameters includes a
 second gap penalty and a second substitution penalty; and the first gap penalty>the second
 gap penalty
- the sequence reads include sequence reads less than 150 bases in length
- the sequence reads comprise at least one million sequence reads
- storing the reference alignment in the computer readable memory by generating a first compact idiosyncratic gaped element report (CIGAR) string representing the reference alignment and storing the first CIGAR string in a Binary Alignment Map (BAM) format or a sequence alignment map (SAM) format in the computer readable memory
- storing the sequence read alignments in the computer-readable memory by generating second CIGAR strings representing the sequence read alignments and storing the second CIGAR strings in the BAM format or the SAM format in the computer readable memory
- storing results of genotyping the at least some of the sequence reads by generating a plurality of CIGAR strings and storing the plurality of CIGAR strings the computerreadable memory
- the reference genome is a human genome
- the instructions further cause the processor to create a file or variable containing a description of the mutations
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the file or variable is a binary alignment map (BAM) file comprising a Compact Idiosyncratic Gapped Alignment Report (CIGAR) string
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the description of the mutations comprises variant and positional information

Appendix 4 – Trans-ABySS

Natera has not met its burden in showing that the Trans-ABySS analysis pipeline and associated references invalidate any Asserted Claims of the Asserted Patents. Trans-ABySS, as disclosed in Natera's contentions, does not render any claim of the Asserted Patents invalid

because, for example, the references do not disclose, teach, or render obvious alone or in combination with other prior art at least the following:

- a method for accurately identifying differences between a reference human genome and sequence reads obtained from a biological sample
- a method for assembling and aligning a plurality of sequence reads having mutations of different types
- inputting a reference genome and said plurality of sequence reads into a computer system comprising a processor coupled to a non-transitory memory; or performing genotyping by one or more computer software programs executing on at least one computer processor coupled to a computer-readable memory to perform a number of steps; or inputting a reference genome and the plurality of sequence reads into a computer system comprising a non-transitory memory and a processor coupled to the non-transitory memory, wherein the non-transitory memory has instructions stored thereon that, when executed by the processor, cause the processor to perform a number of steps
- identifying a plurality of contig:reference descriptions of mutations by aligning the contig to said reference genome; or aligning the contig to the reference human genome to obtain a reference alignment and storing the reference alignment in the computer-readable memory, the reference alignment indicative of first differences between the contig and the reference human genome; or identifying a plurality of contig-to-reference descriptions of the mutations by aligning the contig to a sequence of the reference genome
- identifying a plurality of read:contig descriptions by aligning each of the plurality of sequence reads to the contig; or aligning the at least some of the sequence reads to the contig to obtain sequence read alignments and storing the sequence read alignments in the computer-readable memory, the sequence read alignments indicative of second differences between the at least some of the sequence reads and the contig; or identifying a plurality of read-to-contig descriptions by aligning each of the at least some of the plurality of sequence reads to the contig
- combining the contig:reference descriptions with the read:contig descriptions to produce read:reference descriptions to map positional information of mutations found in the individual reads relative to the reference
- generating a read-to-reference description by aligning at least one of the plurality of contigto-reference descriptions with a corresponding at least one of the plurality of read-to-contig descriptions, wherein the read-to-reference description maps positional information of the mutations found in at least one of the at least some of the plurality of sequence reads relative to the sequence of the reference genome
- genotyping at least some of the sequence reads using a multi-stage alignment
- genotyping the at least some of the sequence reads by identifying multiple mutations in the
 at least some of the sequence reads based on the first differences and the second differences,
 the genotyping comprising mapping the at least some of the sequence reads to the reference

- genome by combining the reference alignment and the sequence read alignments to determine an identity of each of the multiple mutations and its location in the human reference genome
- sequencing the template nucleic acid by fragmenting the template nucleic acid, attaching the fragments to a surface of channels in a flow cell, and amplifying the attached fragments to create clusters, each cluster comprising a plurality of copies of the same template in one of the channels of the flow cell
- identifying a mutation based on the alignments to the contig and the reference sequence
- identifying a plurality of mutations
- identifying a plurality of mutations, wherein a first mutation is within about 100 nucleotides of a second mutation
- identifying a plurality of mutations, wherein the first mutation is a substitution and the second mutation is a deletion
- identifying a plurality of mutations, wherein the mutation is a deletion at the end of a sequence read
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 100 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 10 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 5 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel are proximal to one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel occurs at an end of a sequence read among the at least some of the sequence reads
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel has a length exceeding a length of one or more of the sequence reads
- aligning the contig to a reference sequence by using a first set of alignment parameters
- aligning each of the plurality of sequence reads to the contig by using a second set of alignment parameters

- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome
- aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome and aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig, wherein the first gap penalty is greater than the second gap penalty
- aligning the contig to a reference sequence by using a first set of alignment parameters and
 aligning each of the plurality of sequence reads to the contig by using a second set of
 alignment parameters, wherein the first set of alignment parameters includes a first gap
 penalty and a first substitution penalty; the second set of alignment parameters includes a
 second gap penalty and a second substitution penalty; and the first gap penalty>the second
 gap penalty
- the sequence reads include sequence reads less than 150 bases in length
- the sequence reads comprise at least one million sequence reads
- storing the reference alignment in the computer readable memory by generating a first compact idiosyncratic gaped element report (CIGAR) string representing the reference alignment and storing the first CIGAR string in a Binary Alignment Map (BAM) format or a sequence alignment map (SAM) format in the computer readable memory
- storing the sequence read alignments in the computer-readable memory by generating second CIGAR strings representing the sequence read alignments and storing the second CIGAR strings in the BAM format or the SAM format in the computer readable memory
- storing results of genotyping the at least some of the sequence reads by generating a
 plurality of CIGAR strings and storing the plurality of CIGAR strings the computerreadable memory
- the instructions further cause the processor to create a file or variable containing a description of the mutations
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the file or variable is a binary alignment map (BAM) file comprising a Compact Idiosyncratic Gapped Alignment Report (CIGAR) string
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the description of the mutations comprises variant and positional information

Appendix 5 – Dindel

Natera has not met its burden in showing that the Dindel program and associated references invalidate any Asserted Claims of the Asserted Patents. Dindel, as disclosed in Natera's

contentions, does not render any claim of the Asserted Patents invalid because, for example, the references do not disclose, teach, or render obvious alone or in combination with other prior art at least the following:

- a method for assembling sequence reads
- a method for accurately identifying differences between a reference human genome and sequence reads obtained from a biological sample
- a method for assembling and aligning a plurality of sequence reads having mutations of different types
- inputting a reference genome and said plurality of sequence reads into a computer system comprising a processor coupled to a non-transitory memory; or performing genotyping by one or more computer software programs executing on at least one computer processor coupled to a computer-readable memory to perform a number of steps; or inputting a reference genome and the plurality of sequence reads into a computer system comprising a non-transitory memory and a processor coupled to the non-transitory memory, wherein the non-transitory memory has instructions stored thereon that, when executed by the processor, cause the processor to perform a number of steps
- assembling a contig from at least some of the plurality of sequence reads; or assembling a
 contig using the at least some of the sequence reads, the contig including information about
 positions of the at least some of the sequence reads relative to each other or to a reference
- identifying a plurality of contig:reference descriptions of mutations by aligning the contig to said reference genome; or aligning the contig to the reference human genome to obtain a reference alignment and storing the reference alignment in the computer-readable memory, the reference alignment indicative of first differences between the contig and the reference human genome; or identifying a plurality of contig-to-reference descriptions of the mutations by aligning the contig to a sequence of the reference genome
- identifying a plurality of read:contig descriptions by aligning each of the plurality of sequence reads to the contig; or aligning the at least some of the sequence reads to the contig to obtain sequence read alignments and storing the sequence read alignments in the computer-readable memory, the sequence read alignments indicative of second differences between the at least some of the sequence reads and the contig; or identifying a plurality of read-to-contig descriptions by aligning each of the at least some of the plurality of sequence reads to the contig
- combining the contig:reference descriptions with the read:contig descriptions to produce read:reference descriptions to map positional information of mutations found in the individual reads relative to the reference
- generating a read-to-reference description by aligning at least one of the plurality of contigto-reference descriptions with a corresponding at least one of the plurality of read-to-contig descriptions, wherein the read-to-reference description maps positional information of the

mutations found in at least one of the at least some of the plurality of sequence reads relative to the sequence of the reference genome

- genotyping at least some of the sequence reads using a multi-stage alignment
- genotyping the at least some of the sequence reads by identifying multiple mutations in the at least some of the sequence reads based on the first differences and the second differences, the genotyping comprising mapping the at least some of the sequence reads to the reference genome by combining the reference alignment and the sequence read alignments to determine an identity of each of the multiple mutations and its location in the human reference genome
- attaching barcode sequences to the template nucleic acid
- assigning the reads to subsets based on the barcode sequences
- assigning the reads to subsets based on the barcode sequences and creating a unique contig for that subset
- creating the contig by overlapping consensus assembly; or assembling the contig comprises overlap consensus assembly
- creating the contig by searching a prefix tree for overlap between the reads; or assembling the contig by searching a prefix tree for overlap between the contig and the sequence of the reference genome
- sequencing the template nucleic acid by fragmenting the template nucleic acid, attaching the fragments to a surface of channels in a flow cell, and amplifying the attached fragments to create clusters, each cluster comprising a plurality of copies of the same template in one of the channels of the flow cell
- identifying a mutation based on the alignments to the contig and the reference sequence
- identifying a plurality of mutations
- identifying a plurality of mutations, wherein a first mutation is within about 100 nucleotides of a second mutation
- identifying a plurality of mutations, wherein the first mutation is a substitution and the second mutation is a deletion
- identifying a plurality of mutations, wherein the mutation is a deletion at the end of a sequence read
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 100 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 10 bases of one another

- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 5 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel are proximal to one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel occurs at an end of a sequence read among the at least some of the sequence reads
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel has a length exceeding a length of one or more of the sequence reads
- aligning the contig to a reference sequence by using a first set of alignment parameters
- aligning each of the plurality of sequence reads to the contig by using a second set of alignment parameters
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome
- aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome and aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig, wherein the first gap penalty is greater than the second gap penalty
- aligning the contig to a reference sequence by using a first set of alignment parameters and
 aligning each of the plurality of sequence reads to the contig by using a second set of
 alignment parameters, wherein the first set of alignment parameters includes a first gap
 penalty and a first substitution penalty; the second set of alignment parameters includes a
 second gap penalty and a second substitution penalty; and the first gap penalty>the second
 gap penalty
- the sequence reads include sequence reads less than 150 bases in length
- the sequence reads comprise at least one million sequence reads
- storing the reference alignment in the computer readable memory by generating a first compact idiosyncratic gaped element report (CIGAR) string representing the reference alignment and storing the first CIGAR string in a Binary Alignment Map (BAM) format or a sequence alignment map (SAM) format in the computer readable memory
- storing the sequence read alignments in the computer-readable memory by generating second CIGAR strings representing the sequence read alignments and storing the second CIGAR strings in the BAM format or the SAM format in the computer readable memory

- storing results of genotyping the at least some of the sequence reads by generating a plurality of CIGAR strings and storing the plurality of CIGAR strings the computer-readable memory
- the reference genome is a human genome
- the instructions further cause the processor to create a file or variable containing a description of the mutations
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the file or variable is a binary alignment map (BAM) file comprising a Compact Idiosyncratic Gapped Alignment Report (CIGAR) string
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the description of the mutations comprises variant and positional information

Appendix 6 – Etter

Natera has not met its burden in showing that Etter invalidates any Asserted Claims of the Asserted Patents. Etter, as disclosed in Natera's contentions, does not render any claim of the Asserted Patents invalid because, for example, the references do not disclose, teach, or render obvious alone or in combination with other prior art at least the following:

- a method for accurately identifying differences between a reference human genome and sequence reads obtained from a biological sample
- a method for assembling and aligning a plurality of sequence reads having mutations of different types
- inputting a reference genome and said plurality of sequence reads into a computer system comprising a processor coupled to a non-transitory memory; or performing genotyping by one or more computer software programs executing on at least one computer processor coupled to a computer-readable memory to perform a number of steps; or inputting a reference genome and the plurality of sequence reads into a computer system comprising a non-transitory memory and a processor coupled to the non-transitory memory, wherein the non-transitory memory has instructions stored thereon that, when executed by the processor, cause the processor to perform a number of steps
- identifying a plurality of contig:reference descriptions of mutations by aligning the contig to said reference genome; or aligning the contig to the reference human genome to obtain a reference alignment and storing the reference alignment in the computer-readable memory, the reference alignment indicative of first differences between the contig and the reference human genome; or identifying a plurality of contig-to-reference descriptions of the mutations by aligning the contig to a sequence of the reference genome

- identifying a plurality of read:contig descriptions by aligning each of the plurality of sequence reads to the contig; or aligning the at least some of the sequence reads to the contig to obtain sequence read alignments and storing the sequence read alignments in the computer-readable memory, the sequence read alignments indicative of second differences between the at least some of the sequence reads and the contig; or identifying a plurality of read-to-contig descriptions by aligning each of the at least some of the plurality of sequence reads to the contig
- combining the contig:reference descriptions with the read:contig descriptions to produce read:reference descriptions to map positional information of mutations found in the individual reads relative to the reference
- generating a read-to-reference description by aligning at least one of the plurality of contigto-reference descriptions with a corresponding at least one of the plurality of read-to-contig descriptions, wherein the read-to-reference description maps positional information of the mutations found in at least one of the at least some of the plurality of sequence reads relative to the sequence of the reference genome
- genotyping at least some of the sequence reads using a multi-stage alignment
- genotyping the at least some of the sequence reads by identifying multiple mutations in the at least some of the sequence reads based on the first differences and the second differences, the genotyping comprising mapping the at least some of the sequence reads to the reference genome by combining the reference alignment and the sequence read alignments to determine an identity of each of the multiple mutations and its location in the human reference genome
- attaching barcode sequences to the template nucleic acid
- assigning the reads to subsets based on the barcode sequences
- assigning the reads to subsets based on the barcode sequences and creating a unique contig for that subset
- sequencing the template nucleic acid by fragmenting the template nucleic acid, attaching the fragments to a surface of channels in a flow cell, and amplifying the attached fragments to create clusters, each cluster comprising a plurality of copies of the same template in one of the channels of the flow cell
- identifying a mutation based on the alignments to the contig and the reference sequence
- identifying a plurality of mutations
- identifying a plurality of mutations, wherein a first mutation is within about 100 nucleotides of a second mutation
- identifying a plurality of mutations, wherein the first mutation is a substitution and the second mutation is a deletion
- identifying a plurality of mutations, wherein the mutation is a deletion at the end of a sequence read

- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 100 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 10 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 5 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel are proximal to one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel occurs at an end of a sequence read among the at least some of the sequence reads
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel has a length exceeding a length of one or more of the sequence reads
- aligning the contig to a reference sequence by using a first set of alignment parameters
- aligning each of the plurality of sequence reads to the contig by using a second set of alignment parameters
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome
- aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome and aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig, wherein the first gap penalty is greater than the second gap penalty
- aligning the contig to a reference sequence by using a first set of alignment parameters and
 aligning each of the plurality of sequence reads to the contig by using a second set of
 alignment parameters, wherein the first set of alignment parameters includes a first gap
 penalty and a first substitution penalty; the second set of alignment parameters includes a
 second gap penalty and a second substitution penalty; and the first gap penalty>the second
 gap penalty
- the sequence reads include sequence reads less than 150 bases in length

- the sequence reads comprise at least one million sequence reads
- storing the reference alignment in the computer readable memory by generating a first compact idiosyncratic gaped element report (CIGAR) string representing the reference alignment and storing the first CIGAR string in a Binary Alignment Map (BAM) format or a sequence alignment map (SAM) format in the computer readable memory
- storing the sequence read alignments in the computer-readable memory by generating second CIGAR strings representing the sequence read alignments and storing the second CIGAR strings in the BAM format or the SAM format in the computer readable memory
- storing results of genotyping the at least some of the sequence reads by generating a plurality of CIGAR strings and storing the plurality of CIGAR strings the computer-readable memory
- the reference genome is a human genome
- the instructions further cause the processor to create a file or variable containing a description of the mutations
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the file or variable is a binary alignment map (BAM) file comprising a Compact Idiosyncratic Gapped Alignment Report (CIGAR) string
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the description of the mutations comprises variant and positional information

Appendix 7 – Illumina GA

Natera has not met its burden in showing that Illumina GA and associated references invalidate any Asserted Claims of the Asserted Patents. Illumina GA, as disclosed in Natera's contentions, does not render any claim of the Asserted Patents invalid because, for example, the references do not disclose, teach, or render obvious alone or in combination with other prior art at least the following:

- a method for accurately identifying differences between a reference human genome and sequence reads obtained from a biological sample
- a method for assembling and aligning a plurality of sequence reads having mutations of different types
- inputting a reference genome and said plurality of sequence reads into a computer system comprising a processor coupled to a non-transitory memory; or performing genotyping by one or more computer software programs executing on at least one computer processor coupled to a computer-readable memory to perform a number of steps; or inputting a

- reference genome and the plurality of sequence reads into a computer system comprising a non-transitory memory and a processor coupled to the non-transitory memory, wherein the non-transitory memory has instructions stored thereon that, when executed by the processor, cause the processor to perform a number of steps
- identifying a plurality of contig:reference descriptions of mutations by aligning the contig to said reference genome; or aligning the contig to the reference human genome to obtain a reference alignment and storing the reference alignment in the computer-readable memory, the reference alignment indicative of first differences between the contig and the reference human genome; or identifying a plurality of contig-to-reference descriptions of the mutations by aligning the contig to a sequence of the reference genome
- identifying a plurality of read:contig descriptions by aligning each of the plurality of sequence reads to the contig; or aligning the at least some of the sequence reads to the contig to obtain sequence read alignments and storing the sequence read alignments in the computer-readable memory, the sequence read alignments indicative of second differences between the at least some of the sequence reads and the contig; or identifying a plurality of read-to-contig descriptions by aligning each of the at least some of the plurality of sequence reads to the contig
- combining the contig:reference descriptions with the read:contig descriptions to produce read:reference descriptions to map positional information of mutations found in the individual reads relative to the reference
- generating a read-to-reference description by aligning at least one of the plurality of contigto-reference descriptions with a corresponding at least one of the plurality of read-to-contig descriptions, wherein the read-to-reference description maps positional information of the mutations found in at least one of the at least some of the plurality of sequence reads relative to the sequence of the reference genome
- genotyping at least some of the sequence reads using a multi-stage alignment
- genotyping the at least some of the sequence reads by identifying multiple mutations in the at least some of the sequence reads based on the first differences and the second differences, the genotyping comprising mapping the at least some of the sequence reads to the reference genome by combining the reference alignment and the sequence read alignments to determine an identity of each of the multiple mutations and its location in the human reference genome
- attaching barcode sequences to the template nucleic acid
- assigning the reads to subsets based on the barcode sequences
- assigning the reads to subsets based on the barcode sequences and creating a unique contig for that subset
- sequencing the template nucleic acid by fragmenting the template nucleic acid, attaching the fragments to a surface of channels in a flow cell, and amplifying the attached fragments to create clusters, each cluster comprising a plurality of copies of the same template in one of the channels of the flow cell

- identifying a mutation based on the alignments to the contig and the reference sequence
- identifying a plurality of mutations
- identifying a plurality of mutations, wherein a first mutation is within about 100 nucleotides of a second mutation
- identifying a plurality of mutations, wherein the first mutation is a substitution and the second mutation is a deletion
- identifying a plurality of mutations, wherein the mutation is a deletion at the end of a sequence read
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 100 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 10 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 5 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel are proximal to one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel occurs at an end of a sequence read among the at least some of the sequence reads
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel has a length exceeding a length of one or more of the sequence reads
- aligning the contig to a reference sequence by using a first set of alignment parameters
- aligning each of the plurality of sequence reads to the contig by using a second set of alignment parameters
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome
- aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome and aligning, using a second substitution probability and a second

- gap penalty, the at least some of the sequence reads to the contig, wherein the first gap penalty is greater than the second gap penalty
- aligning the contig to a reference sequence by using a first set of alignment parameters and
 aligning each of the plurality of sequence reads to the contig by using a second set of
 alignment parameters, wherein the first set of alignment parameters includes a first gap
 penalty and a first substitution penalty; the second set of alignment parameters includes a
 second gap penalty and a second substitution penalty; and the first gap penalty>the second
 gap penalty
- the sequence reads include sequence reads less than 150 bases in length
- the sequence reads comprise at least one million sequence reads
- storing the reference alignment in the computer readable memory by generating a first compact idiosyncratic gaped element report (CIGAR) string representing the reference alignment and storing the first CIGAR string in a Binary Alignment Map (BAM) format or a sequence alignment map (SAM) format in the computer readable memory
- storing the sequence read alignments in the computer-readable memory by generating second CIGAR strings representing the sequence read alignments and storing the second CIGAR strings in the BAM format or the SAM format in the computer readable memory
- storing results of genotyping the at least some of the sequence reads by generating a
 plurality of CIGAR strings and storing the plurality of CIGAR strings the computerreadable memory
- the instructions further cause the processor to create a file or variable containing a description of the mutations
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the file or variable is a binary alignment map (BAM) file comprising a Compact Idiosyncratic Gapped Alignment Report (CIGAR) string
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the description of the mutations comprises variant and positional information

Appendix 8 – George

Natera has not met its burden in showing that George invalidates any Asserted Claims of the Asserted Patents. George, as disclosed in Natera's contentions, does not render any claim of the Asserted Patents invalid because, for example, the references do not disclose, teach, or render obvious alone or in combination with other prior art at least the following:

• a method for accurately identifying differences between a reference human genome and sequence reads obtained from a biological sample

- a method for assembling and aligning a plurality of sequence reads having mutations of different types
- obtaining nucleic acid from the biological sample obtained from the human subject
- inputting a reference genome and said plurality of sequence reads into a computer system comprising a processor coupled to a non-transitory memory; or performing genotyping by one or more computer software programs executing on at least one computer processor coupled to a computer-readable memory to perform a number of steps; or inputting a reference genome and the plurality of sequence reads into a computer system comprising a non-transitory memory and a processor coupled to the non-transitory memory, wherein the non-transitory memory has instructions stored thereon that, when executed by the processor, cause the processor to perform a number of steps
- identifying a plurality of contig:reference descriptions of mutations by aligning the contig to said reference genome; or aligning the contig to the reference human genome to obtain a reference alignment and storing the reference alignment in the computer-readable memory, the reference alignment indicative of first differences between the contig and the reference human genome; or identifying a plurality of contig-to-reference descriptions of the mutations by aligning the contig to a sequence of the reference genome
- identifying a plurality of read:contig descriptions by aligning each of the plurality of sequence reads to the contig; or aligning the at least some of the sequence reads to the contig to obtain sequence read alignments and storing the sequence read alignments in the computer-readable memory, the sequence read alignments indicative of second differences between the at least some of the sequence reads and the contig; or identifying a plurality of read-to-contig descriptions by aligning each of the at least some of the plurality of sequence reads to the contig
- combining the contig:reference descriptions with the read:contig descriptions to produce read:reference descriptions to map positional information of mutations found in the individual reads relative to the reference
- generating a read-to-reference description by aligning at least one of the plurality of contigto-reference descriptions with a corresponding at least one of the plurality of read-to-contig descriptions, wherein the read-to-reference description maps positional information of the mutations found in at least one of the at least some of the plurality of sequence reads relative to the sequence of the reference genome
- genotyping at least some of the sequence reads using a multi-stage alignment
- genotyping the at least some of the sequence reads by identifying multiple mutations in the at least some of the sequence reads based on the first differences and the second differences, the genotyping comprising mapping the at least some of the sequence reads to the reference genome by combining the reference alignment and the sequence read alignments to determine an identity of each of the multiple mutations and its location in the human reference genome
- attaching barcode sequences to the template nucleic acid

- assigning the reads to subsets based on the barcode sequences
- assigning the reads to subsets based on the barcode sequences and creating a unique contig for that subset
- creating the contig by overlapping consensus assembly; or assembling the contig comprises overlap consensus assembly
- creating the contig by searching a prefix tree for overlap between the reads; or assembling the contig by searching a prefix tree for overlap between the contig and the sequence of the reference genome
- sequencing the template nucleic acid by fragmenting the template nucleic acid, attaching the fragments to a surface of channels in a flow cell, and amplifying the attached fragments to create clusters, each cluster comprising a plurality of copies of the same template in one of the channels of the flow cell
- identifying a mutation based on the alignments to the contig and the reference sequence
- identifying a plurality of mutations
- identifying a plurality of mutations, wherein a first mutation is within about 100 nucleotides of a second mutation
- identifying a plurality of mutations, wherein the first mutation is a substitution and the second mutation is a deletion
- identifying a plurality of mutations, wherein the mutation is a deletion at the end of a sequence read
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 100 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 10 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 5 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel are proximal to one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel occurs at an end of a sequence read among the at least some of the sequence reads

- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel has a length exceeding a length of one or more of the sequence reads
- aligning the contig to a reference sequence by using a first set of alignment parameters
- aligning each of the plurality of sequence reads to the contig by using a second set of alignment parameters
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome
- aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome and aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig, wherein the first gap penalty is greater than the second gap penalty
- aligning the contig to a reference sequence by using a first set of alignment parameters and aligning each of the plurality of sequence reads to the contig by using a second set of alignment parameters, wherein the first set of alignment parameters includes a first gap penalty and a first substitution penalty; the second set of alignment parameters includes a second gap penalty and a second substitution penalty; and the first gap penalty>the second gap penalty
- the sequence reads include sequence reads less than 150 bases in length
- the sequence reads comprise at least one million sequence reads
- storing the reference alignment in the computer readable memory by generating a first compact idiosyncratic gaped element report (CIGAR) string representing the reference alignment and storing the first CIGAR string in a Binary Alignment Map (BAM) format or a sequence alignment map (SAM) format in the computer readable memory
- storing the sequence read alignments in the computer-readable memory by generating second CIGAR strings representing the sequence read alignments and storing the second CIGAR strings in the BAM format or the SAM format in the computer readable memory
- storing results of genotyping the at least some of the sequence reads by generating a plurality of CIGAR strings and storing the plurality of CIGAR strings the computerreadable memory
- the instructions further cause the processor to create a file or variable containing a description of the mutations
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the file or variable is a binary alignment map (BAM) file comprising a Compact Idiosyncratic Gapped Alignment Report (CIGAR) string

• the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the description of the mutations comprises variant and positional information

Appendix 9 – Li

Natera has not met its burden in showing that Li invalidates any Asserted Claims of the Asserted Patents. Li, as disclosed in Natera's contentions, does not render any claim of the Asserted Patents invalid because, for example, the references do not disclose, teach, or render obvious alone or in combination with other prior art at least the following:

- a method for accurately identifying differences between a reference human genome and sequence reads obtained from a biological sample
- a method for assembling and aligning a plurality of sequence reads having mutations of different types
- inputting a reference genome and said plurality of sequence reads into a computer system comprising a processor coupled to a non-transitory memory; or performing genotyping by one or more computer software programs executing on at least one computer processor coupled to a computer-readable memory to perform a number of steps; or inputting a reference genome and the plurality of sequence reads into a computer system comprising a non-transitory memory and a processor coupled to the non-transitory memory, wherein the non-transitory memory has instructions stored thereon that, when executed by the processor, cause the processor to perform a number of steps
- identifying a plurality of contig:reference descriptions of mutations by aligning the contig to said reference genome; or aligning the contig to the reference human genome to obtain a reference alignment and storing the reference alignment in the computer-readable memory, the reference alignment indicative of first differences between the contig and the reference human genome; or identifying a plurality of contig-to-reference descriptions of the mutations by aligning the contig to a sequence of the reference genome
- identifying a plurality of read:contig descriptions by aligning each of the plurality of sequence reads to the contig; or aligning the at least some of the sequence reads to the contig to obtain sequence read alignments and storing the sequence read alignments in the computer-readable memory, the sequence read alignments indicative of second differences between the at least some of the sequence reads and the contig; or identifying a plurality of read-to-contig descriptions by aligning each of the at least some of the plurality of sequence reads to the contig
- combining the contig:reference descriptions with the read:contig descriptions to produce read:reference descriptions to map positional information of mutations found in the individual reads relative to the reference

- generating a read-to-reference description by aligning at least one of the plurality of contigto-reference descriptions with a corresponding at least one of the plurality of read-to-contig descriptions, wherein the read-to-reference description maps positional information of the mutations found in at least one of the at least some of the plurality of sequence reads relative to the sequence of the reference genome
- genotyping at least some of the sequence reads using a multi-stage alignment
- genotyping the at least some of the sequence reads by identifying multiple mutations in the at least some of the sequence reads based on the first differences and the second differences, the genotyping comprising mapping the at least some of the sequence reads to the reference genome by combining the reference alignment and the sequence read alignments to determine an identity of each of the multiple mutations and its location in the human reference genome
- attaching barcode sequences to the template nucleic acid
- assigning the reads to subsets based on the barcode sequences
- assigning the reads to subsets based on the barcode sequences and creating a unique contig for that subset
- sequencing the template nucleic acid by fragmenting the template nucleic acid, attaching the fragments to a surface of channels in a flow cell, and amplifying the attached fragments to create clusters, each cluster comprising a plurality of copies of the same template in one of the channels of the flow cell
- identifying a mutation based on the alignments to the contig and the reference sequence
- identifying a plurality of mutations
- identifying a plurality of mutations, wherein a first mutation is within about 100 nucleotides of a second mutation
- identifying a plurality of mutations, wherein the first mutation is a substitution and the second mutation is a deletion
- identifying a plurality of mutations, wherein the mutation is a deletion at the end of a sequence read
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 100 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 10 bases of one another

- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 5 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel are proximal to one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel occurs at an end of a sequence read among the at least some of the sequence reads
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel has a length exceeding a length of one or more of the sequence reads
- aligning the contig to a reference sequence by using a first set of alignment parameters
- aligning each of the plurality of sequence reads to the contig by using a second set of alignment parameters
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome
- aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome and aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig, wherein the first gap penalty is greater than the second gap penalty
- aligning the contig to a reference sequence by using a first set of alignment parameters and
 aligning each of the plurality of sequence reads to the contig by using a second set of
 alignment parameters, wherein the first set of alignment parameters includes a first gap
 penalty and a first substitution penalty; the second set of alignment parameters includes a
 second gap penalty and a second substitution penalty; and the first gap penalty>the second
 gap penalty
- the sequence reads include sequence reads less than 150 bases in length
- the sequence reads comprise at least one million sequence reads
- storing the reference alignment in the computer readable memory by generating a first compact idiosyncratic gaped element report (CIGAR) string representing the reference alignment and storing the first CIGAR string in a Binary Alignment Map (BAM) format or a sequence alignment map (SAM) format in the computer readable memory
- storing the sequence read alignments in the computer-readable memory by generating second CIGAR strings representing the sequence read alignments and storing the second CIGAR strings in the BAM format or the SAM format in the computer readable memory

- storing results of genotyping the at least some of the sequence reads by generating a plurality of CIGAR strings and storing the plurality of CIGAR strings the computer-readable memory
- the instructions further cause the processor to create a file or variable containing a description of the mutations
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the file or variable is a binary alignment map (BAM) file comprising a Compact Idiosyncratic Gapped Alignment Report (CIGAR) string
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the description of the mutations comprises variant and positional information

Appendix 10 – Schwartz

Natera has not met its burden in showing that Schwartz invalidates any Asserted Claims of the Asserted Patents. Schwartz, as disclosed in Natera's contentions, does not render any claim of the Asserted Patents invalid because, for example, the references do not disclose, teach, or render obvious alone or in combination with other prior art at least the following:

- a method for accurately identifying differences between a reference human genome and sequence reads obtained from a biological sample
- a method for assembling and aligning a plurality of sequence reads having mutations of different types
- obtaining nucleic acid from the biological sample obtained from the human subject
- inputting a reference genome and said plurality of sequence reads into a computer system comprising a processor coupled to a non-transitory memory; or performing genotyping by one or more computer software programs executing on at least one computer processor coupled to a computer-readable memory to perform a number of steps; or inputting a reference genome and the plurality of sequence reads into a computer system comprising a non-transitory memory and a processor coupled to the non-transitory memory, wherein the non-transitory memory has instructions stored thereon that, when executed by the processor, cause the processor to perform a number of steps
- identifying a plurality of contig:reference descriptions of mutations by aligning the contig to said reference genome; or aligning the contig to the reference human genome to obtain a reference alignment and storing the reference alignment in the computer-readable memory, the reference alignment indicative of first differences between the contig and the reference human genome; or identifying a plurality of contig-to-reference descriptions of the mutations by aligning the contig to a sequence of the reference genome

- identifying a plurality of read:contig descriptions by aligning each of the plurality of sequence reads to the contig; or aligning the at least some of the sequence reads to the contig to obtain sequence read alignments and storing the sequence read alignments in the computer-readable memory, the sequence read alignments indicative of second differences between the at least some of the sequence reads and the contig; or identifying a plurality of read-to-contig descriptions by aligning each of the at least some of the plurality of sequence reads to the contig
- combining the contig:reference descriptions with the read:contig descriptions to produce read:reference descriptions to map positional information of mutations found in the individual reads relative to the reference
- generating a read-to-reference description by aligning at least one of the plurality of contigto-reference descriptions with a corresponding at least one of the plurality of read-to-contig descriptions, wherein the read-to-reference description maps positional information of the mutations found in at least one of the at least some of the plurality of sequence reads relative to the sequence of the reference genome
- genotyping at least some of the sequence reads using a multi-stage alignment
- genotyping the at least some of the sequence reads by identifying multiple mutations in the at least some of the sequence reads based on the first differences and the second differences, the genotyping comprising mapping the at least some of the sequence reads to the reference genome by combining the reference alignment and the sequence read alignments to determine an identity of each of the multiple mutations and its location in the human reference genome
- attaching barcode sequences to the template nucleic acid
- assigning the reads to subsets based on the barcode sequences
- assigning the reads to subsets based on the barcode sequences and creating a unique contig
 for that subset
- sequencing the template nucleic acid by fragmenting the template nucleic acid, attaching the fragments to a surface of channels in a flow cell, and amplifying the attached fragments to create clusters, each cluster comprising a plurality of copies of the same template in one of the channels of the flow cell
- creating the contig by overlapping consensus assembly; or assembling the contig comprises overlap consensus assembly
- creating the contig by searching a prefix tree for overlap between the reads; or assembling the contig by searching a prefix tree for overlap between the contig and the sequence of the reference genome
- identifying a mutation based on the alignments to the contig and the reference sequence
- identifying a plurality of mutations
- identifying a plurality of mutations, wherein a first mutation is within about 100 nucleotides of a second mutation

- identifying a plurality of mutations, wherein the first mutation is a substitution and the second mutation is a deletion
- identifying a plurality of mutations, wherein the mutation is a deletion at the end of a sequence read
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 100 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 10 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 5 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel are proximal to one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel occurs at an end of a sequence read among the at least some of the sequence reads
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel has a length exceeding a length of one or more of the sequence reads
- sequencing the template nucleic acid by sequencing-by-synthesis
- sequencing the template nucleic acid by next generation sequencing
- aligning the contig to a reference sequence by using a first set of alignment parameters
- aligning each of the plurality of sequence reads to the contig by using a second set of alignment parameters
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome
- aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome and aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig, wherein the first gap penalty is greater than the second gap penalty

- aligning the contig to a reference sequence by using a first set of alignment parameters and
 aligning each of the plurality of sequence reads to the contig by using a second set of
 alignment parameters, wherein the first set of alignment parameters includes a first gap
 penalty and a first substitution penalty; the second set of alignment parameters includes a
 second gap penalty and a second substitution penalty; and the first gap penalty>the second
 gap penalty
- the sequence reads include sequence reads less than 150 bases in length
- the sequence reads comprise at least one million sequence reads
- storing the reference alignment in the computer readable memory by generating a first compact idiosyncratic gaped element report (CIGAR) string representing the reference alignment and storing the first CIGAR string in a Binary Alignment Map (BAM) format or a sequence alignment map (SAM) format in the computer readable memory
- storing the sequence read alignments in the computer-readable memory by generating second CIGAR strings representing the sequence read alignments and storing the second CIGAR strings in the BAM format or the SAM format in the computer readable memory
- storing results of genotyping the at least some of the sequence reads by generating a plurality of CIGAR strings and storing the plurality of CIGAR strings the computer-readable memory
- the reference genome is a human genome
- the instructions further cause the processor to create a file or variable containing a description of the mutations
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the file or variable is a binary alignment map (BAM) file comprising a Compact Idiosyncratic Gapped Alignment Report (CIGAR) string
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the description of the mutations comprises variant and positional information

Appendix 11 – Reinhardt

Natera has not met its burden in showing that Reinhardt invalidates any Asserted Claims of the Asserted Patents. Reinhardt, as disclosed in Natera's contentions, does not render any claim of the Asserted Patents invalid because, for example, the references do not disclose, teach, or render obvious alone or in combination with other prior art at least the following:

• a method for accurately identifying differences between a reference human genome and sequence reads obtained from a biological sample

- a method for assembling and aligning a plurality of sequence reads having mutations of different types
- obtaining nucleic acid from the biological sample obtained from the human subject
- inputting a reference genome and said plurality of sequence reads into a computer system comprising a processor coupled to a non-transitory memory; or performing genotyping by one or more computer software programs executing on at least one computer processor coupled to a computer-readable memory to perform a number of steps; or inputting a reference genome and the plurality of sequence reads into a computer system comprising a non-transitory memory and a processor coupled to the non-transitory memory, wherein the non-transitory memory has instructions stored thereon that, when executed by the processor, cause the processor to perform a number of steps
- identifying a plurality of contig:reference descriptions of mutations by aligning the contig to said reference genome; or aligning the contig to the reference human genome to obtain a reference alignment and storing the reference alignment in the computer-readable memory, the reference alignment indicative of first differences between the contig and the reference human genome; or identifying a plurality of contig-to-reference descriptions of the mutations by aligning the contig to a sequence of the reference genome
- identifying a plurality of read:contig descriptions by aligning each of the plurality of sequence reads to the contig; or aligning the at least some of the sequence reads to the contig to obtain sequence read alignments and storing the sequence read alignments in the computer-readable memory, the sequence read alignments indicative of second differences between the at least some of the sequence reads and the contig; or identifying a plurality of read-to-contig descriptions by aligning each of the at least some of the plurality of sequence reads to the contig
- combining the contig:reference descriptions with the read:contig descriptions to produce read:reference descriptions to map positional information of mutations found in the individual reads relative to the reference
- generating a read-to-reference description by aligning at least one of the plurality of contigto-reference descriptions with a corresponding at least one of the plurality of read-to-contig descriptions, wherein the read-to-reference description maps positional information of the mutations found in at least one of the at least some of the plurality of sequence reads relative to the sequence of the reference genome
- genotyping at least some of the sequence reads using a multi-stage alignment
- genotyping the at least some of the sequence reads by identifying multiple mutations in the at least some of the sequence reads based on the first differences and the second differences, the genotyping comprising mapping the at least some of the sequence reads to the reference genome by combining the reference alignment and the sequence read alignments to determine an identity of each of the multiple mutations and its location in the human reference genome
- attaching barcode sequences to the template nucleic acid

- assigning the reads to subsets based on the barcode sequences
- assigning the reads to subsets based on the barcode sequences and creating a unique contig for that subset
- sequencing the template nucleic acid by fragmenting the template nucleic acid, attaching
 the fragments to a surface of channels in a flow cell, and amplifying the attached fragments
 to create clusters, each cluster comprising a plurality of copies of the same template in one
 of the channels of the flow cell
- creating the contig by overlapping consensus assembly; or assembling the contig comprises overlap consensus assembly
- creating the contig by searching a prefix tree for overlap between the reads; or assembling the contig by searching a prefix tree for overlap between the contig and the sequence of the reference genome
- identifying a mutation based on the alignments to the contig and the reference sequence
- identifying a plurality of mutations
- identifying a plurality of mutations, wherein a first mutation is within about 100 nucleotides of a second mutation
- identifying a plurality of mutations, wherein the first mutation is a substitution and the second mutation is a deletion
- identifying a plurality of mutations, wherein the mutation is a deletion at the end of a sequence read
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 100 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 10 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 5 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel are proximal to one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel occurs at an end of a sequence read among the at least some of the sequence reads

- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel has a length exceeding a length of one or more of the sequence reads
- aligning the contig to a reference sequence by using a first set of alignment parameters
- aligning each of the plurality of sequence reads to the contig by using a second set of alignment parameters
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome
- aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome and aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig, wherein the first gap penalty is greater than the second gap penalty
- aligning the contig to a reference sequence by using a first set of alignment parameters and
 aligning each of the plurality of sequence reads to the contig by using a second set of
 alignment parameters, wherein the first set of alignment parameters includes a first gap
 penalty and a first substitution penalty; the second set of alignment parameters includes a
 second gap penalty and a second substitution penalty; and the first gap penalty>the second
 gap penalty
- the sequence reads include sequence reads less than 150 bases in length
- the sequence reads comprise at least one million sequence reads
- storing the reference alignment in the computer readable memory by generating a first compact idiosyncratic gaped element report (CIGAR) string representing the reference alignment and storing the first CIGAR string in a Binary Alignment Map (BAM) format or a sequence alignment map (SAM) format in the computer readable memory
- storing the sequence read alignments in the computer-readable memory by generating second CIGAR strings representing the sequence read alignments and storing the second CIGAR strings in the BAM format or the SAM format in the computer readable memory
- storing results of genotyping the at least some of the sequence reads by generating a
 plurality of CIGAR strings and storing the plurality of CIGAR strings the computerreadable memory
- the reference genome is a human genome
- the instructions further cause the processor to create a file or variable containing a description of the mutations
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the file or variable is a binary alignment map (BAM) file comprising a Compact Idiosyncratic Gapped Alignment Report (CIGAR) string

• the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the description of the mutations comprises variant and positional information

<u>Appendix 12 – WO '206</u>

Natera has not met its burden in showing that WO '206 and other related references invalidate any Asserted Claims of the Asserted Patents. WO '206, as disclosed in Natera's contentions, does not render any claim of the Asserted Patents invalid because, for example, the references do not disclose, teach, or render obvious alone or in combination with other prior art at least the following:

- a method for accurately identifying differences between a reference human genome and sequence reads obtained from a biological sample
- a method for assembling and aligning a plurality of sequence reads having mutations of different types
- inputting a reference genome and said plurality of sequence reads into a computer system comprising a processor coupled to a non-transitory memory; or performing genotyping by one or more computer software programs executing on at least one computer processor coupled to a computer-readable memory to perform a number of steps; or inputting a reference genome and the plurality of sequence reads into a computer system comprising a non-transitory memory and a processor coupled to the non-transitory memory, wherein the non-transitory memory has instructions stored thereon that, when executed by the processor, cause the processor to perform a number of steps
- identifying a plurality of contig:reference descriptions of mutations by aligning the contig to said reference genome; or aligning the contig to the reference human genome to obtain a reference alignment and storing the reference alignment in the computer-readable memory, the reference alignment indicative of first differences between the contig and the reference human genome; or identifying a plurality of contig-to-reference descriptions of the mutations by aligning the contig to a sequence of the reference genome
- identifying a plurality of read:contig descriptions by aligning each of the plurality of sequence reads to the contig; or aligning the at least some of the sequence reads to the contig to obtain sequence read alignments and storing the sequence read alignments in the computer-readable memory, the sequence read alignments indicative of second differences between the at least some of the sequence reads and the contig; or identifying a plurality of read-to-contig descriptions by aligning each of the at least some of the plurality of sequence reads to the contig

- combining the contig:reference descriptions with the read:contig descriptions to produce read:reference descriptions to map positional information of mutations found in the individual reads relative to the reference
- generating a read-to-reference description by aligning at least one of the plurality of contigto-reference descriptions with a corresponding at least one of the plurality of read-to-contig descriptions, wherein the read-to-reference description maps positional information of the mutations found in at least one of the at least some of the plurality of sequence reads relative to the sequence of the reference genome
- genotyping at least some of the sequence reads using a multi-stage alignment
- genotyping the at least some of the sequence reads by identifying multiple mutations in the at least some of the sequence reads based on the first differences and the second differences, the genotyping comprising mapping the at least some of the sequence reads to the reference genome by combining the reference alignment and the sequence read alignments to determine an identity of each of the multiple mutations and its location in the human reference genome
- attaching barcode sequences to the template nucleic acid
- assigning the reads to subsets based on the barcode sequences
- assigning the reads to subsets based on the barcode sequences and creating a unique contig for that subset
- sequencing the template nucleic acid by fragmenting the template nucleic acid, attaching the fragments to a surface of channels in a flow cell, and amplifying the attached fragments to create clusters, each cluster comprising a plurality of copies of the same template in one of the channels of the flow cell
- identifying a mutation based on the alignments to the contig and the reference sequence
- identifying a plurality of mutations
- identifying a plurality of mutations, wherein a first mutation is within about 100 nucleotides of a second mutation
- identifying a plurality of mutations, wherein the first mutation is a substitution and the second mutation is a deletion
- identifying a plurality of mutations, wherein the mutation is a deletion at the end of a sequence read
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 100 bases of one another

- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 10 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 5 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel are proximal to one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel occurs at an end of a sequence read among the at least some of the sequence reads
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel has a length exceeding a length of one or more of the sequence reads
- aligning the contig to a reference sequence by using a first set of alignment parameters
- aligning each of the plurality of sequence reads to the contig by using a second set of alignment parameters
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome
- aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome and aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig, wherein the first gap penalty is greater than the second gap penalty
- aligning the contig to a reference sequence by using a first set of alignment parameters and
 aligning each of the plurality of sequence reads to the contig by using a second set of
 alignment parameters, wherein the first set of alignment parameters includes a first gap
 penalty and a first substitution penalty; the second set of alignment parameters includes a
 second gap penalty and a second substitution penalty; and the first gap penalty>the second
 gap penalty
- the sequence reads include sequence reads less than 150 bases in length
- the sequence reads comprise at least one million sequence reads
- storing the reference alignment in the computer readable memory by generating a first compact idiosyncratic gaped element report (CIGAR) string representing the reference alignment and storing the first CIGAR string in a Binary Alignment Map (BAM) format or a sequence alignment map (SAM) format in the computer readable memory

- storing the sequence read alignments in the computer-readable memory by generating second CIGAR strings representing the sequence read alignments and storing the second CIGAR strings in the BAM format or the SAM format in the computer readable memory
- storing results of genotyping the at least some of the sequence reads by generating a
 plurality of CIGAR strings and storing the plurality of CIGAR strings the computerreadable memory
- the instructions further cause the processor to create a file or variable containing a description of the mutations
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the file or variable is a binary alignment map (BAM) file comprising a Compact Idiosyncratic Gapped Alignment Report (CIGAR) string
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the description of the mutations comprises variant and positional information

<u>Appendix 13 – Schneeberger</u>

Natera has not met its burden in showing that Schneeberger invalidates any Asserted Claims of the Asserted Patents. Schneeberger, as disclosed in Natera's contentions, does not render any claim of the Asserted Patents invalid because, for example, the references do not disclose, teach, or render obvious alone or in combination with other prior art at least the following:

- a method for accurately identifying differences between a reference human genome and sequence reads obtained from a biological sample
- a method for assembling and aligning a plurality of sequence reads having mutations of different types
- obtaining nucleic acid from the biological sample obtained from the human subject
- inputting a reference genome and said plurality of sequence reads into a computer system comprising a processor coupled to a non-transitory memory; or performing genotyping by one or more computer software programs executing on at least one computer processor coupled to a computer-readable memory to perform a number of steps; or inputting a reference genome and the plurality of sequence reads into a computer system comprising a non-transitory memory and a processor coupled to the non-transitory memory, wherein the non-transitory memory has instructions stored thereon that, when executed by the processor, cause the processor to perform a number of steps
- identifying a plurality of contig:reference descriptions of mutations by aligning the contig to said reference genome; or aligning the contig to the reference human genome to obtain a reference alignment and storing the reference alignment in the computer-readable memory, the reference alignment indicative of first differences between the contig and the

- reference human genome; or identifying a plurality of contig-to-reference descriptions of the mutations by aligning the contig to a sequence of the reference genome
- identifying a plurality of read:contig descriptions by aligning each of the plurality of sequence reads to the contig; or aligning the at least some of the sequence reads to the contig to obtain sequence read alignments and storing the sequence read alignments in the computer-readable memory, the sequence read alignments indicative of second differences between the at least some of the sequence reads and the contig; or identifying a plurality of read-to-contig descriptions by aligning each of the at least some of the plurality of sequence reads to the contig
- combining the contig:reference descriptions with the read:contig descriptions to produce read:reference descriptions to map positional information of mutations found in the individual reads relative to the reference
- generating a read-to-reference description by aligning at least one of the plurality of contigto-reference descriptions with a corresponding at least one of the plurality of read-to-contig descriptions, wherein the read-to-reference description maps positional information of the mutations found in at least one of the at least some of the plurality of sequence reads relative to the sequence of the reference genome
- genotyping at least some of the sequence reads using a multi-stage alignment
- genotyping the at least some of the sequence reads by identifying multiple mutations in the at least some of the sequence reads based on the first differences and the second differences, the genotyping comprising mapping the at least some of the sequence reads to the reference genome by combining the reference alignment and the sequence read alignments to determine an identity of each of the multiple mutations and its location in the human reference genome
- attaching barcode sequences to the template nucleic acid
- assigning the reads to subsets based on the barcode sequences
- assigning the reads to subsets based on the barcode sequences and creating a unique contig for that subset
- sequencing the template nucleic acid by fragmenting the template nucleic acid, attaching the fragments to a surface of channels in a flow cell, and amplifying the attached fragments to create clusters, each cluster comprising a plurality of copies of the same template in one of the channels of the flow cell
- identifying a mutation based on the alignments to the contig and the reference sequence
- identifying a plurality of mutations
- identifying a plurality of mutations, wherein a first mutation is within about 100 nucleotides of a second mutation
- identifying a plurality of mutations, wherein the first mutation is a substitution and the second mutation is a deletion

- identifying a plurality of mutations, wherein the mutation is a deletion at the end of a sequence read
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 100 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 10 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 5 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel are proximal to one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel occurs at an end of a sequence read among the at least some of the sequence reads
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel has a length exceeding a length of one or more of the sequence reads
- aligning the contig to a reference sequence by using a first set of alignment parameters
- aligning each of the plurality of sequence reads to the contig by using a second set of alignment parameters
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome
- aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome and aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig, wherein the first gap penalty is greater than the second gap penalty
- aligning the contig to a reference sequence by using a first set of alignment parameters and aligning each of the plurality of sequence reads to the contig by using a second set of alignment parameters, wherein the first set of alignment parameters includes a first gap penalty and a first substitution penalty; the second set of alignment parameters includes a second gap penalty and a second substitution penalty; and the first gap penalty>the second gap penalty

- the sequence reads include sequence reads less than 150 bases in length
- the sequence reads comprise at least one million sequence reads
- storing the reference alignment in the computer readable memory by generating a first compact idiosyncratic gaped element report (CIGAR) string representing the reference alignment and storing the first CIGAR string in a Binary Alignment Map (BAM) format or a sequence alignment map (SAM) format in the computer readable memory
- storing the sequence read alignments in the computer-readable memory by generating second CIGAR strings representing the sequence read alignments and storing the second CIGAR strings in the BAM format or the SAM format in the computer readable memory
- storing results of genotyping the at least some of the sequence reads by generating a plurality of CIGAR strings and storing the plurality of CIGAR strings the computer-readable memory
- the reference genome is a human genome
- the instructions further cause the processor to create a file or variable containing a description of the mutations
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the file or variable is a binary alignment map (BAM) file comprising a Compact Idiosyncratic Gapped Alignment Report (CIGAR) string
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the description of the mutations comprises variant and positional information

Appendix 14 – HC 2011

Natera has not met its burden in showing that HaplotypeCaller (2011) (HC 2011) or HaplotypeCaller (2012) (HC 2012) invalidates any Asserted Claims of the Asserted Patents. HC 2011 or HC 2012, as disclosed in Natera's contentions, does not render any claim of the Asserted Patents invalid because, for example, the the references do not disclose, teach, or render obvious alone or in combination with other prior art at least the following.

- obtaining a sample comprising template nucleic acid; or obtaining nucleic acid from the biological sample obtained from the human subject
- sequencing the template nucleic acid to generate a plurality of sequence reads; or sequencing the sample to generate the plurality of sequence reads
- inputting a reference genome and said plurality of sequence reads into a computer system comprising a processor coupled to a non-transitory memory; or performing genotyping by one or more computer software programs executing on at least one computer processor

coupled to a computer-readable memory to perform a number of steps; or inputting a reference genome and the plurality of sequence reads into a computer system comprising a non-transitory memory and a processor coupled to the non-transitory memory, wherein the non-transitory memory has instructions stored thereon that, when executed by the processor, cause the processor to perform a number of steps

- identifying a plurality of contig:reference descriptions of mutations by aligning the contig to said reference genome; or aligning the contig to the reference human genome to obtain a reference alignment and storing the reference alignment in the computer-readable memory, the reference alignment indicative of first differences between the contig and the reference human genome; or identifying a plurality of contig-to-reference descriptions of the mutations by aligning the contig to a sequence of the reference genome
- identifying a plurality of read:contig descriptions by aligning each of the plurality of
 sequence reads to the contig; or aligning the at least some of the sequence reads to the
 contig to obtain sequence read alignments and storing the sequence read alignments in the
 computer-readable memory, the sequence read alignments indicative of second differences
 between the at least some of the sequence reads and the contig; or identifying a plurality of
 read-to-contig descriptions by aligning each of the at least some of the plurality of sequence
 reads to the contig
- combining the contig:reference descriptions with the read:contig descriptions to produce read:reference descriptions to map positional information of mutations found in the individual reads relative to the reference
- generating a read-to-reference description by aligning at least one of the plurality of contigto-reference descriptions with a corresponding at least one of the plurality of read-to-contig descriptions, wherein the read-to-reference description maps positional information of the mutations found in at least one of the at least some of the plurality of sequence reads relative to the sequence of the reference genome
- genotyping at least some of the sequence reads using a multi-stage alignment
- genotyping the at least some of the sequence reads by identifying multiple mutations in the at least some of the sequence reads based on the first differences and the second differences, the genotyping comprising mapping the at least some of the sequence reads to the reference genome by combining the reference alignment and the sequence read alignments to determine an identity of each of the multiple mutations and its location in the human reference genome
- attaching barcode sequences to the template nucleic acid
- assigning the reads to subsets based on the barcode sequences
- assigning the reads to subsets based on the barcode sequences and creating a unique contig for that subset
- sequencing the template nucleic acid by fragmenting the template nucleic acid, attaching
 the fragments to a surface of channels in a flow cell, and amplifying the attached fragments
 to create clusters, each cluster comprising a plurality of copies of the same template in one
 of the channels of the flow cell

- identifying a mutation based on the alignments to the contig and the reference sequence
- identifying a plurality of mutations
- identifying a plurality of mutations, wherein a first mutation is within about 100 nucleotides of a second mutation
- identifying a plurality of mutations, wherein the first mutation is a substitution and the second mutation is a deletion
- identifying a plurality of mutations, wherein the mutation is a deletion at the end of a sequence read
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 100 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 10 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel occur within 5 bases of one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first substitution and the first indel are proximal to one another
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel occurs at an end of a sequence read among the at least some of the sequence reads
- identifying a plurality of mutations, wherein the multiple mutations including mutations of different types including a first substitution and a first indel and the first indel has a length exceeding a length of one or more of the sequence reads
- sequencing the template nucleic acid by sequencing-by-synthesis
- sequencing the template nucleic acid by next generation sequencing
- aligning the contig to a reference sequence by using a first set of alignment parameters
- aligning each of the plurality of sequence reads to the contig by using a second set of alignment parameters
- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome
- aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig

- aligning, using a first substitution probability and a first gap penalty, the contig to the reference human genome and aligning, using a second substitution probability and a second gap penalty, the at least some of the sequence reads to the contig, wherein the first gap penalty is greater than the second gap penalty
- aligning the contig to a reference sequence by using a first set of alignment parameters and
 aligning each of the plurality of sequence reads to the contig by using a second set of
 alignment parameters, wherein the first set of alignment parameters includes a first gap
 penalty and a first substitution penalty; the second set of alignment parameters includes a
 second gap penalty and a second substitution penalty; and the first gap penalty>the second
 gap penalty
- the sequence reads include sequence reads less than 150 bases in length
- the sequence reads comprise at least one million sequence reads
- storing the reference alignment in the computer readable memory by generating a first compact idiosyncratic gaped element report (CIGAR) string representing the reference alignment and storing the first CIGAR string in a Binary Alignment Map (BAM) format or a sequence alignment map (SAM) format in the computer readable memory
- storing the sequence read alignments in the computer-readable memory by generating second CIGAR strings representing the sequence read alignments and storing the second CIGAR strings in the BAM format or the SAM format in the computer readable memory
- storing results of genotyping the at least some of the sequence reads by generating a plurality of CIGAR strings and storing the plurality of CIGAR strings the computer-readable memory
- the template nucleic acid is DNA or RNA
- the reference genome is a human genome
- the instructions further cause the processor to create a file or variable containing a description of the mutations, wherein the file or variable is a binary alignment map (BAM) file comprising a Compact Idiosyncratic Gapped Alignment Report (CIGAR) string

Further, the accused functionality is Sentieon's DNAseq and TNseq which are based on

the methodology of recent versions of GATK HaplotypeCaller and Mutect 2, respectively, not the old versions of HaplotypeCaller. Natera alleges that HC 2011 and HC 2012 work in the same way as current HaplotypeCaller. However, HaplotypeCaller has undergone changes and improvements that have changed key functionalities. An examination of the GATK source code since version 2.0 and the repository history, which are publicly available, reveal that HC 2011 and HC 2012 miss key functionalities of the patented methods. For example, a new bubble concept

was introduced to HaplotypeCaller in GATK 2.4. The bubble concept is similar to the intermediary "contig" in the patented methods. This concept is absent from HC 2011 or HC 2012. As another example, key functions that generate read:reference alignment by mapping read:haplotype alignment to haplotype:reference alignment were introduced to HaplotypeCaller in GATK 2.5. These functions are absent from HC 2011 or HC 2012.

102(g)

Conception is defined as when the inventor formed in his or her mind "a definite and permanent idea of the complete operative invention, as it is hereafter to be applied in practice," which idea is "so clearly defined in the inventor's mind that only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation." *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, 40 F.3d 1223, 1228, 32 U.S.P.Q.2d 1915 (Fed. Cir. 1994). Natera relies on two whiteboard images (NTRA-INVT-00411179, NTRA-INVT-00411182) taken by Ryan Poplin to show conception. However, these images do not show Ryan Poplin and others at the Broad Institute formed in their mind a definite and permanent idea of the complete operative invention. To the extent Natera alleges that these images correspond to HC 2011 and HC 2012, they still do not support conception at least because (1) HC 2011 and HC 2012 do not disclose the claimed invention as shown by the discussion above regarding Appendix 14; and (2) these images do not show the functionalities of HC 2011 or HC 2012 in sufficient details.

In general, to constitute an actual reduction to practice of the invention the party seeking to prove the reduction must show (1) that it constructed an invention meeting all of the limitations of the claim at issue, or if in an interference all of the limitations of the interference count; and (2) that the invention would work for its intended purpose. Natera relies on HC 2011 and HC 2012 as alternative reduction to practice. As discussed above regarding Appendix 14, HC 2011 and

HC 2012 do not meet all of the limitations of the claims at issue. Further, Natera also has not shown that the invention worked for its intended purpose.

Natera relies on a number of Broad documents to show diligence. Natera has not provided any explanations about how the cited Broad documents support that Broad Institute did not abandon, suppress, or conceal the alleged early versions of HaplotypeCaller.

Natera's Contentions Based on 35 U.S.C. § 112

The Asserted Patents are presumed valid pursuant to 35 U.S.C. § 282. Natera has not met its burden in showing with clear and convincing evidence that the Asserted Claims of the Asserted Patents are invalid for lack of written description, lack of enablement, or indefiniteness.

Natera's contentions did no more than listing a number of terms and alleging they do not satisfy the § 112 requirements with no explanations. "The patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation." *Falkner v. Inglis*, 448 F.3d 1357, 1366 (Fed. Cir. 2006). For example, Natera's contentions fail to explain why a person of ordinary skill in the art would not recognize from reading the specification that the inventors possessed the full scope of the claimed invention. Also for example, Natera's contentions fail to conduct any analysis using the *Wands* factors to show a person of ordinary skill in the art would not make and use the full scope of the claimed invention without undue experimentation. Also for example, Natera's contentions likewise fail to explain why the claim terms do not "inform those skilled in the art about the scope of the invention

with reasonable certainty." Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 901, 910 (2014).

The Asserted Patents provide sufficient § 112 support to the claim terms. The following charts identify exemplary disclosures from the specification that provides § 112 support to the claim terms identified in Natera's contentions Part V.C. The burden of proof is on Natera. Invitae reserves right to rely on additional disclosure from the specification and file history of the patents, state of art or understanding of a skilled artisan at the relevant time, other facts and factors considered by law, and expert discovery.

Claim Terms	Asserted Patents	Exemplary Disclosure in the '799 Patent
Contig assembly and alignment	799, 308, 863	Fig. 1, Fig. 2, 2:30-5:39, 12:34-
elements, generally		21:63
Template nucleic acid	799, 308, 863	2:30-5:39, 5:60-9:35
Plurality of sequence reads	799, 308, 863	2:30-5:39, 13:25-16:43
Description, descriptions,	799, 863	2:30-5:39, 20:32-48, 21:5-27
descriptions of		
mutations		
Mutation(s)	799, 308, 863	2:30-5:39, 20:32-23:5
identifying a plurality of	799	2:30-5:39, 16:44-20:48
contig:reference descriptions of		
mutations by aligning the contig		
to said reference genome		
combining the contig:reference	799	2:30-5:39, 21:12-22:44
descriptions with the read:contig		
descriptions of mutations to		
produce read:reference		
descriptions to map positional		
information of mutations found		
in the individual reads relative to		
the reference	=00	
identifying a mutation based on	799	2:30-5:39, 21:12-23:5
the alignments to the contig and		
the reference sequence		
mutations are identified,	799	2:30-5:39, 21:12-23:5
identifying a mutation		
a plurality of mutations are identified	799	2:30-5:39, 22:45-23:5

a first mutation is within about	799	2:30-5:39, 22:45-23:5
100 nucleotides of a second		
mutation		
reference sequence	799	2:30-5:39
within about 100	799	2:30-5:39, 22:45-23:5
an end of a sequence read	799, 308	2:30-5:39, 22:45-23:5
first substitution penalty	799	2:30-5:39, 16:44-21:11
the first set of alignment	799	2:30-5:39, 16:44-21:11
parameters includes a first gap		
penalty ; the second set of		
alignment parameters includes a		
second gap penalty ; and the		
first gap penalty>the second gap		
penalty		
Nucleic acid	308	2:30-5:39, 5:60-9:35
Multi-stage alignment	308	2:30-5:39, 16:44-21:11
Alignment(s)	308	2:30-5:39, 16:44-22:57
genotyping the at least some of	308	2:30-5:39, 21:12-23:5
the sequence reads by identifying		
multiple mutations in the at least		
some of the sequence reads based		
on the first differences and the		
second differences		
mapping the at least some of the	308	2:30-5:39, 21:12-22:44
sequence reads to the reference		
genome by combining the		
reference alignment and the		
sequence read alignments		
to determine an identity of each		
of the multiple mutations and its		
location in the human reference		
genome		
proximal to one another	308	2:30-5:39, 22:45-23:5
CIGAR strings	308	Fig. 2, 10:41-62, 21:64-22:44
wherein the first plurality of	308	2:30-5:39, 16:44-21:11
alignment parameters includes a		
first gap penalty, the second		
plurality of alignment parameters		
includes a second gap penalty		
., and the first gap penalty is		
greater than the second gap		
penalty		
RNA	863	2:30-5:39, 5:60-9:35
generating a read-to-reference	863	2:30-5:39, 16:44-20:48
description by aligning at least		,
1 7 8 8	I .	J

one of the plurality of contig-to- reference descriptions with a corresponding at least one of the plurality of read-to-contig descriptions, wherein the read- toreference description maps positional information of the mutations found in at least one of the at least some of the plurality of sequence reads relative to the sequence of the		
reference genome		
identifying the mutations	863	2:30-5:39, 21:12-23:5
identifying the mutations based on one or more alignments between the contig and the sequence of the reference genome	863	2:30-5:39, 21:12-23:5
wherein the first plurality of alignment parameters includes a first gap penalty and a first substitution probability, the second plurality of alignment parameters includes a second gap penalty and a second substitution probability, and the first gap penalty is greater than the second gap penalty	863	2:30-5:39, 16:44-21:11

Natera's Contentions Based on 35 U.S.C. § 101

Natera's contentions largely recycle its arguments made in its Rule 12(b)(6) motion for all of the Asserted Patents. *See* D.I. 9. The court has found the '799 Patent to be patent eligible under 35 U.S.C. § 101. *See* D.I. 28. For the same reasons, the '308 and '863 Patents are likewise patent eligible. Invitae incorporates by reference and D.I. 13 (Invitae's opposition to Natera's motion to dismiss) and D.I. 28 (memorandum order denying Natera's motion to dismiss).

Invitae further incorporates by reference its responses to Interrogatory Nos. 2 and 13. Invitae further expects to rely on the deposition testimony of Ryan Poplin, Eric Banks, Jared

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 662 of 739 PageID #: 13412

Maguire, Gregory Porreca, Caleb Kennedy, Nirav Malani, Andrea Velenich, Raheleh Salari, Hsin-Ta Wu, and Joshua Paul. Additional information responsive to this interrogatory is expected from expert discovery. Dated: April 28, 2023 Respectfully submitted,

FARNAN LLP

<u>/s/ Brian E. Farnan</u>

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CERTIFICATE OF SERVICE

I, Brian E. Farnan, hereby certify that on April 28, 2023, a copy of Invitae Corporation's Supplemental Responses and Objections to Natera, Inc.'s Second Set of Interrogatories (No. 9) was served on the following as indicated:

Via E-Mail Via E-Mail Karen Jacobs Eric Alan Stone Brian P. Egan Daniel J. Klein Derek J. Fahnestock Ariella C. Barel 1201 North Market Street Eliza P. Strong P.O. Box 1347 GROOMBRIDGE, WU, BAUGHMAN & Wilmington, DE 19899 STONE LLP kjacobs@morrisnichols.com natera-invitae@groombridgewu.com began@morrisnichols.com dfahnestock@morrisnichols.com Attorneys for Defendant Natera, Inc.

Attorneys for Defendant Natera, Inc.

/s/ Brian E. Farnan
Brian E. Farnan (Bar No. 4089)

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

AMERICA HOLDING))
	Plaintiff,) C.A. No. 21-669 (GBW)
V.))
NATERA, INC.))
	Defendant.	
LABORATORY COR AMERICA HOLDING)))
	Plaintiff,) C.A. No. 21-1635 (GBW)
v.)
NATERA, INC.		<i>)</i>)
	Defendant.	,)

PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION IN LIMINE NO. 1:
PRECLUDE EVIDENCE OR ARGUMENT THAT ANTICIPATION BY A PRIOR ART
SYSTEM CANNOT BE ESTABLISHED USING MULTIPLE DOCUMENTS THAT
DESCRIBE THE SYSTEM

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Dated: August 6, 2025

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Attorneys for Plaintiff Laboratory Corporation of America Holdings Natera contends that Labcorp should be precluded from offering evidence or argument that Natera cannot establish anticipation by a prior-art system by relying on multiple references. Whether this is permissible, however, is a pure legal question. If Natera wants a jury instruction on this issue, a motion *in limine* is an inappropriate means to seek such a remedy. Alternatively, if Natera wants summary judgment on this issue, Natera's motion *in limine* is likewise improper. Either way, Natera's motion is improper and should be denied.

I. A MOTION IN LIMINE IS NOT THE APPROPRIATE FORUM FOR THE REMEDY NATERA SEEKS

A "motion *in limine* is appropriate for evidentiary submissions that clearly ought not be presented to the jury because they clearly would be inadmissible for any purpose." *Hologic, Inc. v. Minerva Surgical, Inc.*, 325 F. Supp. 3d 507, 521 (D. Del. 2018) (internal quotations and citations omitted). But rather than requesting a ruling on an evidentiary issue, Natera improperly seeks findings of law and/or fact as to whether its four references that supposedly pertain to NextGENe may be effectively treated as a single reference that describes the NextGENe system.

If Natera wants a *legal* ruling that more than one reference may be combined to establish anticipation when the alleged prior art is a system, its motion *in limine* is improper. This purely legal issue should be addressed not through an *in limine* motion, but through jury instructions.

On the other hand, if Natera's wants a summary judgment on the factual question of whether its four references—and all relied-upon aspects of these references—all pertain not just to NextGENe but the same version of this system, then its motion *in limine* is an improper summary judgment motion that would demand extensive fact-finding and analysis from the Court. Natera's assertion that it is "too late" for Labcorp to challenge that the references are all directed to the same prior-art system ignores that Natera bears the burden on invalidity and that its motion effectively seeks summary judgment on countless factual questions involving the scope and

content of four different prior art references. See Natera's MIL 1 at 1 n.1. This is not appropriate for a motion in limine. See C R Bard Inc. v. AngioDynamics Inc., No. 1:15-cv-218, 2018 WL 3468215, at *4 (D. Del. July 18, 2018) (finding a motion to preclude a plaintiff from attempting to prove an invention date was inappropriate for a motion in limine and is instead a motion for summary judgment); see also Moon Express, Inc. v. Intuitive Machines, LLC, No. 16-cv-344-LPS, 2017 WL 6380750, at *2 (D. Del. Dec. 14, 2017) ("Unlike a summary judgment motion, which is designed to eliminate a trial in cases where there are no genuine issues of fact, a motion in limine is designed to narrow the evidentiary issues for trial and to eliminate unnecessary trial interruptions."). In fact, while Natera now moves in limine, the eligibility of NextGENe as a priorart system through multiple references is a topic that has been raised in connection with summary judgment. See D.I. 225 at 7; see also D.I. 246 at 26; D.I. 266 at 13-14. This confirms that the issue is inappropriate for a motion in limine.

II. NATERA HAS FAILED TO SHOW THAT THE REFERENCES ARE DIRECTED TO THE SAME SYSTEM

Even assuming Natera's motion was the proper subject of a motion *in limine*, it should nonetheless be denied on the merits. A patent challenger must show by "clear and convincing evidence" that a patent is invalid. *Sciele Pharma Inc. v. Lupin Ltd.*, 684 F.3d 1253, 1260 (Fed. Cir. 2012). As part of this burden, Natera must show by clear and convincing evidence that all references it asserts are representative of the NextGENe system as prior art are in fact representative. *See Evolved Wireless, LLC v. Apple, Inc.*, No. 15-cv-543-JFP-SRF, 2019 WL 831112, at *3 (D. Del. Feb. 21, 2019) ("The party challenging the validity of a patent bears the burden of persuasion by clear and convincing evidence on all issues relating to the status of [a reference] as prior art.") (internal quotations and citations omitted). Natera has failed to meet this burden.

To allegedly show invalidity by anticipation, Natera cites four documents that allegedly show the operation of NextGENe. Natera has failed to show by clear and convincing evidence that these references are representative of the NextGENe software for a number of reasons. First, none of the references specify a version of the NextGENe software that is used to perform the described methods. In fact, one reference, U.S. Patent No. 8,271,206 ("Liu"), does not even mention the NextGENe software. Natera has made no showing that any version of the NextGENe software embodies Liu, nor affirmatively shown that the specification of Liu describes any version of the NextGENe software. Second, none of the references describe the entire method of operation of the NextGENe software. Natera does not rely on any source code, product manuals, or any other primary reference describing any version of the NextGENe software to support its claims of anticipation by NextGENe. Third, Natera's cited references range in date from September 2008 to April 2009. As software is ever-changing, it is unclear whether these documents are all representative of the same version of NextGENe and Natera has done nothing to provide clarification on this matter. This is far from clear and convincing evidence, and Natera should not be granted a backdoor summary judgment via a motion in limine.

In sum, Natera's attempt to cobble together a myriad of references to allege anticipation by NextGENe is without merit. *See Apple, Inc. v. Samsung Elecs. Co.*, No. 12-cv-00630-LHK, 2012 WL 2576136, at *3 (N.D. Cal. July 3, 2012) (finding that a post-hoc reconstruction "of how a [prior-art system] might have been constructed does not constitute prior art for purposes of anticipation."). As such, Labcorp should not be precluded from presenting evidence or argument that Natera cannot establish anticipation by a prior-art system through the use of these multiple references.

August 6, 2025

Respectfully submitted,

FARNAN LLP

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CERTIFICATE OF SERVICE

I, Brian E. Farnan, hereby certify that on August 6, 2025, a copy of PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION *IN LIMINE* NO. 1: PRECLUDE EVIDENCE OR ARGUMENT THAT ANTICIPATION BY A PRIOR ART SYSTEM CANNOT BE ESTABLISHED USING MULTIPLE DOCUMENTS THAT DESCRIBE THE SYSTEM was served on the following as indicated:

Via E-Mail Via E-Mail Eric Alan Stone Karen Jacobs (#2881) Daniel J. Klein Brian P. Egan (#6227) Derek J. Fahnestock (#4705) Eliza P. Strong Ariella C. Barel MORRIS, NICHOLS, ARSHT & TUNNELL GROOMBRIDGE, WU, BAUGHMAN & LLP STONE LLP 1201 North Market Street 565 Fifth Avenue, Suite 2900 P.O. Box 1347 New York, NY 10017 Wilmington, DE 19899 (332) 269-0030 (302) 658-9200 eric.stone@groombridgewu.com kjacobs@morrisnichols.com dan.klein@groombridgewu.com began@morrisnichols.com eliza.strong@groombridgewu.com dfahnestock@morrisnichols.com ariella.barel@groombridgewu.com natera-invitae@groombridgewu.com Attorneys for Defendant Natera, Inc.

Attorneys for Defendant Natera, Inc.

/s/ Brian E. Farnan
Brian E. Farnan (Bar No. 4089)

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

C.A. No. 21-cv-669-GBW

C.A. No. 21-cv-1635-GBW

NATERA'S REPLY IN FURTHER SUPPORT OF ITS MOTION TO PRECLUDE LABCORP FROM USING, OR PRESENTING EVIDENCE OR ARGUMENT REGARDING, THE TESTIMONY AND EXPERT REPORTS OF RYAN SULLIVAN

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Karen Jacobs (#2881) Brian P. Egan (#6227) Derek J. Fahnestock (#4705)

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Daniel J. Klein
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Exhibit 20

STONE LLP 565 Fifth Avenue, Suite 2900 New York, NY 10017 (332) 269-0030

Joshua A. Rosefelt GROOMBRIDGE, WU, BAUGHMAN & STONE LLP 801 17th Street, NW, Suite 1050 Washington, DC 20006 (202) 505-5830 Attorneys for Defendant Natera, Inc.

Natera seeks to preclude Labcorp from introducing opinions offered in a different case, *ArcherDX*, by an expert, Ryan Sullivan, Ph.D., who has not been retained and will not testify in this case. Labcorp responds that because 1) its damages expert Mr. Alexander Clemons apparently read some of Dr. Sullivan's prior testimony, *but did not opine about it*, Labcorp has a blank slate to discuss Dr. Sullivan's opinions; and 2) that Natera failed to timely object to the admissibility of Dr. Sullivan's opinions. Labcorp is wrong on both points.

First, Mr. Clemons did not disclose opinions about—or rely on, quote, or even refer to—Dr. Sullivan's testimony. Labcorp rests its entire argument on the fact that Dr. Sullivan's ArcherDX testimony is on Mr. Clemons's "documents considered" list. Opp. at 2 (citing Ex. A). If that matters at all, it cuts against Labcorp: it means Mr. Clemons considered Dr. Sullivan's testimony and then chose not to offer an opinion about it. The inclusion of Dr. Sullivan's ArcherDX testimony on Mr. Clemons's materials considered list does not give Labcorp any basis, much less a blank slate, to introduce and discuss Dr. Sullivan's prior opinions here. Fed. R Civ. P. 26(a)(2) requires that experts testifying under FRE 703 disclose "all opinions the witness will express" 90 days before trial. Mr. Clemons disclosed no opinions about Dr. Sullivan in his reports, and Labcorp points to no passages in the body of Mr. Clemons's reports where he even mentions Dr. Sullivan.

Second, Natera's objection is timely. Natera objected to the admissibility of Dr. Sullivan's testimony and reports in a letter filed with the Court on June 23, 2023, **after** Mr. Clemons's report was served on June 16, 2023. Ex. 1 at 2. ("Dr. Sullivan's materials would not be admissible at trial in this case."). At the parties' July 21, 2023 hearing, the Court deferred ruling on the admissibility of Dr. Sullivan's opinions. Ex. 2 12:22–13:2 ("whether or not it's admissible is another question."). Natera's timely motion appropriately re-raises this admissibility question.

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

N,)
ntiff,)
) C.A. No. 21-669 (GBW)
)) HIGHLY CONFIDENTIAL) FILED UNDER SEAL
endant.)
N,)
ntiff,)
) C.A. No. 21-1635 (GBW)
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endant.)
	endant. N, ntiff,

LETTER TO THE HONORABLE GREGORY B. WILLIAMS FROM DEREK J. FAHNESTOCK REGARDING DISCOVERY DISPUTE

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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Attorneys for Defendant Natera, Inc.

OF COUNSEL:

Eric Alan Stone Daniel J. Klein Eliza P. Strong Ariella C. Barel GROOMBRIDGE, WU, BAUGHMAN & STONE LLP 565 Fifth Avenue, Suite 2900 New York, NY 10017 (332) 269-0030

Natera respectfully submits this answering letter regarding the pending discovery dispute.

Natera's Position Regarding Production of Altera Sales Data

Invitae first sought "financials relating to sales of" Natera's Altera product (which is not accused of infringement in this case) in an email on May 5, 2023. Invitae has never served any formal discovery request for these data, which should be reason alone to deny Invitae's request. Worse, Invitae's only basis for seeking this information is its mischaracterization of the February 9, 2023 deposition of David Bessette, Natera's Vice President of Finance. Although Invitae says Mr. Bessette testified that he actually testified tha

Natera's Position Regarding ArcherDX Materials

Natera recognizes that the Court is presiding over the *ArcherDX* action between Natera and Invitae. But that is a separate lawsuit, and Natera's lead counsel in this case does not represent Natera in that case and is not under the Protective Order in that case. Invitae's request for *ArcherDX* materials should be denied even without regard to the specific materials themselves.

First, the *ArcherDX* materials Invitae seeks were designated as Highly Confidential—Attorney's Eyes' Only pursuant to the Protective Order in that case. *See* C.A. No. 12-125, D.I. 69 (Exhibit B). That Order prohibits the use of such materials for any purpose other than to litigate *that case. Id.* at Section 7.1.

The above-captioned actions were filed well after the commencement of the *ArcherDX* case, but there is no cross-use provision in the Protective Order negotiated and entered for this case authorizing the use of information obtained in the *ArcherDX* case, *see* C.A. No. 21-669, D.I. 46, and neither party argued for the consolidation of these cases with the *ArcherDX* case. If Invitae had wanted to treat the cases as the same, it had every opportunity to propose that at the outset to avoid duplicative discovery. Instead, Invitae and its counsel apparently *want* duplicative discovery, to have multiple bites at the apple. That is unfair.

Another issue stemming from the separateness of the actions is that, while counsel for the various Invitae entities (which includes ArcherDX) is the same, Natera's lead counsel here is not involved in the *ArcherDX* litigation. Invitae's counsel should not be using in this litigation the confidential information it obtained in the *ArcherDX* litigation under the terms of the protective order in that case. Yet, Invitae is using the contents of those confidential materials from *ArcherDX* in *this case* to argue why they are relevant and discoverable in the present motion. Moreover, Natera's lead counsel here cannot view in this case the information designated by the Invitae

entities as confidential in the ArcherDX case. Invitae would thus be getting disproportionate discovery if its motion were granted—the ability to see, use, and understand the full context of materials while Natera's lead counsel here would only have access to the portions of those materials that do not contain ArcherDX's confidential information.

Dr. Sullivan's Materials from *ArcherDX*. Invitae's request for Dr. Sullivan's materials is an attempt to circumvent the Court's previous order denying Invitae's motion to compel production of certain agreements involving Natera. See D.I. 177. Invitae protests that it does not seek the "exhibits" to Dr. Sullivan's materials that overlap with the subject matter of its previous, unsuccessful motion to compel, but Dr. Sullivan's reports and deposition testimony in the ArcherDX case refer to the materials as to which this Court denied Invitae's prior request. Invitae merely seeks to gain in a different form the discovery this Court already denied.

Moreover, Dr. Sullivan's materials would not be admissible at trial in this case. He is not an expert in this case and will not be testifying at trial. Although Invitae relies on the *Pernix* case (attached as Exhibit C) to demonstrate why its motion should succeed, Pernix actually proves the opposite—that this discovery is not reasonably calculated to lead to the discovery of admissible evidence (a burden of showing that Invitae bears but fails to address in its motion). As discussed below, these materials themselves are not admissible, and fact discovery is closed, so they cannot "lead" to the discovery of admissible evidence. AgroFresh Inc. v. Essentiv LLC, C.A. No. 16-662-MN-SRF, 2018 WL 9578196, at *2 (D. Del. Dec. 11, 2018) ("To achieve the policy goals of both Rule 26 and Rule 408, courts within the Third Circuit require the moving party to make a 'particularized showing' that the evidence sought is relevant and reasonably calculated to lead to the discovery of admissible evidence.").

Pernix makes clear that an expert's reports or opinions cannot be deemed the statements of a party's agent or employee within the meaning of Fed. R. Evid. 801(d)(2)(C) or (D). Pernix Ireland v. Alvogen, 316 F. Supp. 3d 816, 819-23 (D. Del. 2018); see also Kirk v. Raymark Indus., Inc., 61 F.3d 147, 164 (3d Cir. 1995); VM Techs., LLC v. Intel Corp., C. A. No. 15-33-RGA, 2017 WL 1753999, at *2 (D. Del. May 1, 2017) (report of expert not called to testify was inadmissible hearsay). Dr. Sullivan's opinions and testimony in ArcherDX cannot be admissible in this case as the statements of a Natera agent or employee.

Pernix also provides a roadmap, which Invitae ignores, for when an expert's prior opinions may be deemed the adoptive admissions of a party under Fed. R. Evid. 801(d)(2)(B). Specifically, the opinions of an expert retained by a party in a previous case may be deemed adoptive admissions when the party calls the expert to give testimony to prove a particular fact. 316 F. Supp. at 825. But, as *Pernix* makes clear, the expert's report itself is not evidence of a party's adoption of those opinions. See Pernix, 316 F. Supp. at 825-26. Invitae has made no effort to identify which portions of Dr. Sullivan's prior reports and deposition testimony would bear indicia of having been adopted by Natera based on Dr. Sullivan's later trial testimony in ArcherDX. Invitae's request thus seeks discovery that would not lead to admissible evidence as a matter of law.

To the extent Invitae suggests that Dr. Sullivan's prior reports or deposition testimony could be used to impeach a different expert in this case, *Pernix* also answers that question in the #: 13429

negative: "[I]f statements by a declarant are inadmissible as hearsay, those statements cannot be used to cross-examine a different witness at trial." Id. at 826.

John Fesko and Solomon Moshkevich's Deposition Transcripts and Exhibits from ArcherDX. Invitae first requested these materials in March 2023. After Invitae made that request, Invitae deposed Messrs. Fesko and Moshkevich in this case, in their individual capacities and as Rule 30(b)(6) witnesses. It had a full and fair opportunity to cover any legitimate subject matter.

Invitae's motion makes no effort to explain what non-duplicative information in their ArcherDX depositions would be relevant here and could not have been obtained in their depositions in this case. Invitae has failed to carry its burden to show that the requested information is relevant to "either the claims, defenses, or the subject matter of the litigation" or why its probative value outweighs the costs and burdens producing it would impose on Natera. See Inventio, 662 F. Supp. 2d at 380-81 (noting "[a]lthough the scope of discovery is broad, it is not unlimited"); see also INVISTA N. Am. S.à.r.l. v. M&G USA Corp., C.A. No. 11-1007-SLR-CJB, 2013 WL 12171721, at *2 (D. Del. June 25, 2013).

Michael Brophy's Deposition Transcript and Exhibits from ArcherDX. Natera has not identified Mr. Brophy as a witness in this case and will not be calling him to trial. If Invitae wanted to seek his testimony in this case, it should have noticed his deposition. It chose not to do so. It is hard to imagine anything Mr. Brophy might know that Invitae did not cover in its 56 requests for production, 25 interrogatories, 24 requests for admission, and nine deposition notices under Rules 30(b)(1) and 30(b)(6), but if it needed Mr. Brophy, too, it could have sought his deposition. The ArcherDX case is not a de facto expansion of the deposition limitations and discovery taken in this case. Invitae's only argument now is that Mr. Brophy is a Natera employee who testified about Signatera and PCM in the ArcherDX case. That explains why Invitae might have wanted to depose him, not why it should get to use in this case his deposition from the ArcherDX case. That falls well short of demonstrating that the requested information is relevant to the claims.

Respectfully,

/s/ Derek J. Fahnestock

Derek J. Fahnestock (#4705)

DJF/rah **Enclosures**

cc: All Counsel of Record (via electronic mail)

EXHIBIT 2

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1	IN THE UNITED STATES DISTRICT COURT
2	IN AND FOR THE DISTRICT OF DELAWARE
3)
4	INVITAE CORPORATION,)
5) Civil Action Nos. Plaintiff,) 21-cv-669-GBW and
6	v.) 21-cv-1635-GBW)
7	NATERA, INC.,)
8	Defendant.
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11	Wilmington, Delaware Friday, July 21, 2023
12	Teleconference Transcript
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14	BEFORE: HONORABLE GREGORY B. WILLIAMS UNITED STATES DISTRICT COURT JUDGE
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25	Michele L. Rolfe, RPR, CRR

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 682 of 739 PageID 3432 **APPEARANCES** 1 MR. WALTER: Good morning, Your Honor. This is 2 FARNAN, LLP 2 Derek Walter. I'll start out with that issue, as you BY: MICHAEL J. FARNAN, ESQ. 3 3 requested. 4 There's, I think, a key point that needs to be WEIL GOTSHAL & MANGES, LLP BY: DEREK WALTER, ESQ. 5 5 stated upfront that might have been implicit in the brief, Counsel on behalf of Invitae Corporation 6 but might not have been explicit. As the Court knows, we 7 just completed a trial between Invitae and Natera, and the 7 MORRIS NICHOLS ARSHT & TUNNELL, LLP 8 BY: DEREK JAMES FAHNESTOCK, ESQ. Court might recall that in that trial Natera relied upon the 8 9 -and-9 Archer Beacon Dixon agreement through its expert to procure 10 GROOMBRIDGE WU damages, and particularly argued that this agreement 10 ELIZA P. STRONG, ESQ. 11 ERIC ALAN STONE, ESQ. 11 warranted a 20 percent royalty for cancer testing products. 12 Counsel for Natera, Inc. 12 Well, it is fair play and the key point that the Court 13 13 should understand is that our expert is now relying upon 14 that very license to seek damages from Natera. The same 14 15 15 license that Natera previously relied upon to seek damages 16 with respect to Invitae. And that's why this material is 16 17 17 highly relevant. 18 18 If that wasn't clear from the papers, it should 19 19 be clear now. We're relying upon that same agreement that 20 20 they relied upon, that's why this discovery is relevant. 21 21 Let me go through the arguments they raised. 22 The first argument that they raised is that Natera's lead 22 23 23 counsel is not under the protective order from that prior 24 24 litigation. And that argument, frankly, is a strange 25 25 argument. Of course, they concede Natera's confidential 5

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1 2 PROCEEDINGS 3 (REPORTER'S NOTE: The following teleconference was held beginning at 10:00 a.m.) THE COURT: Good morning. We're here for a discovery conference in Invitae Corp versus Natera Corp. 6 Civil Action Nos. 21-669 and 21-16345 7 Let's start by having counsel put appearances on 8 9 the record. MR. FARNAN: Good morning, Your Honor. Brian 10 Farnan on behalf of the plaintiff. And with me is Derek 12 Walter from Weil Gotshal. 13 THE COURT: All right. Good morning. 14 Defendants? 15 MS. JACOBS: Good morning, Your Honor, For 16 Natera this is Karen Jacobs and Derek Fahnestock from Morris 17 Nichols. 18 We have on the line with us and will be arguing 19 today are Eric Stone and Eliza Strong from Groombridge Wu. 20 THE COURT: Okay. Good morning 21 All right. We have three issues. So let's start with the first issue dealing with the request of 22 23 plaintiff to compel the expert reports, deposition testimony 24 and corresponding exhibits of Natera's damages expert Ryan Sullivan from the ArcherDX litigation. 25

information, so to the extent the requested information has 2 Natera's information, Natera's counsel can see that; it's odd to contend that they can't. But the strange concern 3 4 that they seem to have is that they might be prohibited from seeing Invitae's information pursuant to that protective 6 order. Well, it's a strange concern. We're asking them to 7 produce the information. 8 If we thought there was a concern with them 9 seeing the information, we would have said so. Of course 10 Natera's outside counsel can see the information, we want 11 them to produce it to us. So if there's any concern there, 12 let's put that to doubt now; we're granting them permission

They also complain that the protective order prohibits use in another case. Well, that's why we're asking them to produce it. It can't be that you can shield something from forever being used in another case by producing it in a second case, so that's why we're trying to get around this issue. We're asking them to produce it so we can use it in this case.

to see the material so they can produce it to us.

Just picking through their arguments, they cite the AgroFresch case, that's a case about production of settlement agreements where there appears to be a heightened standard. That's not what this is. Okay. This is not a settlement agreement situation.

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admission unless Natera gave that -- called him to give that testimony at trial. And to the extent Natera did so, they have the trial testimony.

And after they see the expert report from us today, there is something that they think is inconsistent with his trial court testimony that is in the expert report, they can -- you know, they can ask us. But the notion that they should -- we should have to produce the expert report and deposition testimony of an expert in another case whom we are not calling in this case is exactly what Judge Bryson held in Pernix is irrelevant. And it can't lead to the discovery of admissible evidence at this point, fact discovery is over.

Let me make one more point because this is a new argument -- forgive me, that I don't think Mr. Walter made in the argument and I don't mean that pergoratively, I just want to make sure I respond to it. The notion that their expert can respond to hearsay because it is hearsay but experts can rely on hearsay, the rule is that experts can rely on hearsay of the type that is usually relied upon by experts in the field. Damages experts can rely on economic analyses, they can rely on the literature. You certainly cannot argue that an expert can rely on another parties' expert report because it is hearsay. The rule is not that experts can use all hearsay of any kind. The rule is that

statements or analysis, they are relying effectively upon 2 what other people in the field have said. And the notion 3 that one expert can't rely upon something that another party 4 is saying is an authority in the field, that's erroneous. 5 Of course one expert can rely upon the statements of someone 6 else who the other party has said is an authority in the 7 field; that's precisely the kind of stuff that experts rely 8 upon when they provide their testimony.

MR. STONE: Your Honor, I know that the Courts don't ordinarily entertain sur-rebuttal, but I must be doing a very bad job today because neither of those is the argument that I made. So just in the interest of full disclosure, the reason that I pointed out it's a different expert is that if it were the same expert, it would be a prior statement of the expert; we would be having a different conservation.

My point is simply it doesn't matter -- the reason that it matters that it's not Dr. Sullivan is that he's not testifying in the case.

And on the hearsay point -- on that I'll stop. We simply just --

THE COURT: Yeah. On this issue I do think it's fair game for Invitae to have access to that information for discovery purposes; whether or not it's admissible is another question. So I'm going to order the production with

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experts can use hearsay of the type ordinarily relied upon 2 by experts in the field. That rule has absolutely no 3 applicability here.

4 THE COURT: All right.

MR. WALTER: Your Honor, this is Derek Walter.

Should i respond briefly to some the points he

7 made? 8

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THE COURT: Yes, you can respond.

MR. WALTER: All right. So as to the first point that the expert that they plan to rely upon in this case is different from the expert that they relied upon in the first case, that's irrelevant.

What matters is Natera would have adopted the statements of their expert and they would have done so in either this trial or the previous trials; it doesn't have to be the same expert. Pernix doesn't say that, neither does Abstracts. In fact, I think in that Abstracts case we cited it was a different expert and that discovery was allowed. So the notion that it has to be the same expert, that's just wrona.

And then finally on the last point, the hearsay point, you know that's incorrect, too. It's incorrect that an expert in one field can't rely upon the testimony or the statements or the opinions of someone else in another field. That's what people do when they rely upon publications or

1 respect to the first request.

Let's move on to the second request.

3 MR. WALTER: Thank you, Your Honor.

4 The second request, I believe you -- the Natera

5 sales data, that's the one I'm going to take next.

6 I'll just stick to the arguments here. The 7 first thing they do is they complain that there's no 8 document request that relevant to this. That was a 9 surprising argument for us to see in this brief because it

10 was not once mentioned during meet and confer. If they 11

really thought that the lack of a document request was a 12 barrier here, they should have said so and we could have

13 remedied. So I think they've waived that argument. But

14 what's also really telling here is they don't submit the

15 document request we have in this case. And if you look at 16 the document request, which are not before the Court, I can

17 only tell you what's there, I think we probably do have

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document requests, Request 20 asks for documents relating to

19 identifying somatic sensations. Request 31 asks for things 20 related to the accused product. And to the extent that's

21 sold as a unit, that would be an accused products. Request

22 42 asks for the same sort of things. So the lack of

23 document request was kind of a strange and surprising 24 argument.

25 Also, they make an argument based on the merits.

_	Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 684 of 739 PageID
١.	³⁰ #: 1 <mark>3434</mark>
1	at 10:38 a.m.)
2	I hereby certify the foregoing is a true
3	and accurate transcript from my stenographic notes in the
4	proceeding.
5	/s/ Michele L. Rolfe, RPR, CRR
	U.S. District Court
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Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 685 of 739 PageID

EXHIBIT 20B

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

C.A. No. 21-cv-669-GBW

v.

NATERA, INC.,

Defendant.

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

C.A. No. 21-cv-1635-GBW

DEFENDANT'S MOTION IN LIMINE NO. 2: PRECLUDE INVITAE FROM USING, OR PRESENTING EVIDENCE OR ARGUMENT REGARDING, THE TESTIMONY AND EXPERT REPORTS OF RYAN SULLIVAN

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

OF COUNSEL:

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Exhibit 20

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Joshua A. Rosefelt GROOMBRIDGE, WU, BAUGHMAN & STONE LLP 801 17th Street, NW, Suite 1050 Washington, DC 20006 (202) 505-5830 Attorneys for Defendant Natera, Inc.

I. INTRODUCTION

Natera respectfully moves to preclude Invitae from using at trial, including presenting evidence or argument regarding, the deposition testimony and expert reports (including supporting materials and exhibits thereto) of Ryan Sullivan, Ph.D. from *Natera, Inc. v. ArcherDX, Inc. et al.*, No. 1:20-cv-125-GBW (D. Del.) (the "*ArcherDX* Case"). Dr. Sullivan's deposition testimony and reports are not admissible here as a matter of law.

II. BACKGROUND

As the Court may remember, Dr. Sullivan was Natera's damages expert in the *ArcherDX* Case. But Dr. Sullivan is not Natera's expert (or anyone's expert) in this case, and the Natera patents asserted and technologies at issue in the *ArcherDX* Case are unrelated to the Invitae patents asserted and technology at issue here. Dr. Sullivan has not submitted reports or testified in this case, has not offered any opinions relating to the Asserted Patents in this case, and will not testify at trial. On June 21, 2023, Invitae, through its counsel who also represent the defendants in the *ArcherDX* Case, moved to compel here the production of Dr. Sullivan's expert reports and related materials and his deposition transcript and its exhibits from *ArcherDX* Case. D.I. 187. The Court granted that motion for only "discovery purposes," noting that "whether or not it's admissible is another question." Ex. A at 12:22–25; *see also* D.I. 192.

Invitae now intends to use Dr. Sullivan's materials at trial in this case, purportedly to impeach Natera's witnesses and to prove the truth of the matters asserted therein. For the reasons set forth below, such testimony and reports, which concerned different patents and technologies, are irrelevant and prohibited as hearsay under the Federal Rules of Evidence and this District's and Circuit's precedents.

III. ARGUMENT

An expert's report and deposition testimony from another litigation are hearsay when offered in a second litigation, in which that expert is not retained or testifying, even if offered against the party that retained that expert in the first case. *Pernix Ireland Pain Dac v. Alvogen Malta Operations Ltd.*, 316 F. Supp. 3d 816, 819 (D. Del. 2018). Yet that is exactly what Invitae proposes to do here: Offer against Natera in this case the expert report and deposition testimony of Natera's former expert, Dr. Sullivan, from the *ArcherDX* Case.

This situation is nearly identical to the facts of *Pernix*, in which the court—after reviewing Delaware and Third Circuit precedents—held that experts' statements from one case could not be used at trial in another case where those experts were not testifying on behalf of the party against whom their statements would be offered. 316 F. Supp. 3d at 828. In *Pernix*, as here, only three exceptions to the hearsay rule were even "arguably pertinent": Rule 801(d)(2)(B) (adoptive admissions), Rule 801(d)(2)(C) (statements authorized by party); Rule 801(d)(2)(D) (statement by party's agent or employee). *Id.* at 819. The *Pernix* court's reasoning for why none of those three exceptions applied is directly on point here.

Rules 801(d)(2)(C) and (D): While the defendant in *Pernix* had retained these experts in the previous case, their roles were "to serve as independent experts, and there [was] no evidentiary basis from which to conclude that either of them is an agent or employee of [the defendant], such that any statement made by the experts within the scope of their employment or agency should be attributable to the principal." *Id.* at 823. That holding applies equally to an expert's prior deposition testimony. *See HTC Corp. v. Telefonaktiebolaget LM Ericsson*, 12 F.4th 476, 489–90 (5th Cir. 2021); *Ochoa-Valenzuela v. Ford Motor Co. Inc.*, 685 F. App'x 551, 554 (9th Cir. 2017); *SanDisk Corp. v. Kingston Tech. Co.*, 863 F. Supp. 2d 815, 818–19 (W.D. Wis. 2012); *see also Kirk v. Raymark Indus., Inc.*, 61 F.3d 147, 164 (3d Cir. 1995) (holding expert's prior trial testimony

in unrelated case inadmissible hearsay against different expert in current case). The same is true here: Dr. Sullivan was retained by Natera to serve as an independent expert. His opinions and deposition testimony are not admissions of Natera or statements of its agent or employee, and are not attributable to Natera for purposes of Rule 801(d)(2)(C) or (D).

Rule 801(d)(2)(B): The *Pernix* court held that the experts' reports were not "adoptive admissions" even though—in the prior case—the defendant had "designat[ed] them as experts, serv[ed] reports from them, ma[de] them available for deposition, and designat[ed] them as trial witnesses." 316 F. Supp. 3d at 825–26. None of these actions, however, was "enough" to show that the defendant "adopted any specific statement contained in the expert reports." *Id.* at 825. And this reasoning also applies with equal strength to a former expert's deposition testimony from a different case. *See HTC Corp.*, 12 F.4th at 490; *Ochoa-Valenzuela*, 685 F. App'x at 554; *SanDisk* 863 F. Supp. 2d at 818–19. Accordingly, that Dr. Sullivan served as an expert for Natera in a previous, unrelated case does not render his statements, whether in the form of his expert report or deposition testimony, adopted by Natera for purposes of Rule 801(d)(2)(B).

Use for Impeachment: Finally, the *Pernix* court ruled that because the former experts' statements from the prior case were inadmissible hearsay, they could not be used to impeach a different witness in the later case. 316 F. 3d at 826, 828 (holding that such use would be "contrary to the principle that, if statements by a declarant are inadmissible as hearsay, those statements cannot be used to cross-examine a different witness at trial"); *see* Fed. R. Evid. 613(b) (allowing impeachment only by testifying witness's *own* prior inconsistent statement). That same principle precludes Invitae's intended use of Dr. Sullivan's prior statements here.

EXHIBIT A

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1	IN THE UNITED STATES DISTRICT COURT
2	IN AND FOR THE DISTRICT OF DELAWARE
3)
4	INVITAE CORPORATION,)
5) Civil Action Nos. Plaintiff,) 21-cv-669-GBW and
6	v.) 21-cv-1635-GBW)
7	NATERA, INC.,)
8	Defendant.
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11	Wilmington, Delaware Friday, July 21, 2023
12	Teleconference Transcript
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14	BEFORE: HONORABLE GREGORY B. WILLIAMS UNITED STATES DISTRICT COURT JUDGE
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25	Michele L. Rolfe, RPR, CRR

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 693 of 739 PageID 3443 APPEARANCES: MR. WALTER: Good morning, Your Honor. This is 2 FARNAN, LLP 2 Derek Walter. I'll start out with that issue, as you BY: MICHAEL J. FARNAN, ESQ. 3 3 requested. 4 There's, I think, a key point that needs to be WEIL GOTSHAL & MANGES, LLP BY: DEREK WALTER, ESQ. 5 5 stated upfront that might have been implicit in the brief, Counsel on behalf of Invitae Corporation 6 but might not have been explicit. As the Court knows, we 7 just completed a trial between Invitae and Natera, and the 7 MORRIS NICHOLS ARSHT & TUNNELL, LLP 8 BY: DEREK JAMES FAHNESTOCK, ESQ. Court might recall that in that trial Natera relied upon the 8 9 -and-9 Archer Beacon Dixon agreement through its expert to procure 10 GROOMBRIDGE WU damages, and particularly argued that this agreement 10 ELIZA P. STRONG, ESQ. 11 ERIC ALAN STONE, ESQ. 11 warranted a 20 percent royalty for cancer testing products. 12 Counsel for Natera, Inc. 12 Well, it is fair play and the key point that the Court 13 13 should understand is that our expert is now relying upon 14 that very license to seek damages from Natera. The same 14 15 15 license that Natera previously relied upon to seek damages 16 with respect to Invitae. And that's why this material is 16 17 17 highly relevant. 18 18 If that wasn't clear from the papers, it should 19 19 be clear now. We're relying upon that same agreement that 20 20 they relied upon, that's why this discovery is relevant. 21 21 Let me go through the arguments they raised. 22 The first argument that they raised is that Natera's lead 22 23 23 counsel is not under the protective order from that prior 24 24 litigation. And that argument, frankly, is a strange 25 25 argument. Of course, they concede Natera's confidential 5

1 2 PROCEEDINGS 3 (REPORTER'S NOTE: The following teleconference was held beginning at 10:00 a.m.) THE COURT: Good morning. We're here for a discovery conference in Invitae Corp versus Natera Corp. 6 Civil Action Nos. 21-669 and 21-16345 7 Let's start by having counsel put appearances on 8 9 the record. MR. FARNAN: Good morning, Your Honor. Brian 10 Farnan on behalf of the plaintiff. And with me is Derek 12 Walter from Weil Gotshal. 13 THE COURT: All right. Good morning. 14 Defendants? 15 MS. JACOBS: Good morning, Your Honor, For 16 Natera this is Karen Jacobs and Derek Fahnestock from Morris 17 Nichols. 18 We have on the line with us and will be arguing 19 today are Eric Stone and Eliza Strong from Groombridge Wu. 20 THE COURT: Okay. Good morning 21 All right. We have three issues. So let's start with the first issue dealing with the request of 22 23 plaintiff to compel the expert reports, deposition testimony

and corresponding exhibits of Natera's damages expert Ryan

Sullivan from the ArcherDX litigation.

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information, so to the extent the requested information has 1 2 Natera's information, Natera's counsel can see that; it's odd to contend that they can't. But the strange concern 3 4 that they seem to have is that they might be prohibited from seeing Invitae's information pursuant to that protective 6 order. Well, it's a strange concern. We're asking them to 7 produce the information. 8 If we thought there was a concern with them 9 seeing the information, we would have said so. Of course 10 Natera's outside counsel can see the information, we want 11 them to produce it to us. So if there's any concern there, 12 let's put that to doubt now; we're granting them permission 13 to see the material so they can produce it to us. 14 They also complain that the protective order 15 prohibits use in another case. Well, that's why we're asking them to produce it. It can't be that you can shield 16 17 something from forever being used in another case by producing it in a second case, so that's why we're trying to 18 19 get around this issue. We're asking them to produce it so 20 we can use it in this case.

Just picking through their arguments, they cite

settlement agreements where there appears to be a heightened

the AgroFresch case, that's a case about production of

standard. That's not what this is. Okay. This is not a

settlement agreement situation.

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Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 694 of 739 PageID

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admission unless Natera gave that -- called him to give that testimony at trial. And to the extent Natera did so, they have the trial testimony.

And after they see the expert report from us today, there is something that they think is inconsistent with his trial court testimony that is in the expert report, they can -- you know, they can ask us. But the notion that they should -- we should have to produce the expert report and deposition testimony of an expert in another case whom we are not calling in this case is exactly what Judge Bryson held in Pernix is irrelevant. And it can't lead to the discovery of admissible evidence at this point, fact discovery is over.

Let me make one more point because this is a new argument -- forgive me, that I don't think Mr. Walter made in the argument and I don't mean that pergoratively, I just want to make sure I respond to it. The notion that their expert can respond to hearsay because it is hearsay but experts can rely on hearsay, the rule is that experts can rely on hearsay of the type that is usually relied upon by experts in the field. Damages experts can rely on economic analyses, they can rely on the literature. You certainly cannot argue that an expert can rely on another parties' expert report because it is hearsay. The rule is not that experts can use all hearsay of any kind. The rule is that

statements or analysis, they are relying effectively upon 2 what other people in the field have said. And the notion 3 that one expert can't rely upon something that another party 4 is saying is an authority in the field, that's erroneous. 5 Of course one expert can rely upon the statements of someone 6 else who the other party has said is an authority in the 7 field; that's precisely the kind of stuff that experts rely

upon when they provide their testimony.

MR. STONE: Your Honor, I know that the Courts don't ordinarily entertain sur-rebuttal, but I must be doing a very bad job today because neither of those is the argument that I made. So just in the interest of full disclosure, the reason that I pointed out it's a different expert is that if it were the same expert, it would be a prior statement of the expert; we would be having a different conservation.

My point is simply it doesn't matter -- the reason that it matters that it's not Dr. Sullivan is that he's not testifying in the case.

And on the hearsay point -- on that I'll stop. We simply just --

THE COURT: Yeah. On this issue I do think it's fair game for Invitae to have access to that information for discovery purposes; whether or not it's admissible is another question. So I'm going to order the production with

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experts can use hearsay of the type ordinarily relied upon 2 by experts in the field. That rule has absolutely no 3 applicability here.

4 THE COURT: All right.

MR. WALTER: Your Honor, this is Derek Walter.

Should i respond briefly to some the points he

7 made? 8

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THE COURT: Yes, you can respond.

MR. WALTER: All right. So as to the first point that the expert that they plan to rely upon in this case is different from the expert that they relied upon in the first case, that's irrelevant.

What matters is Natera would have adopted the statements of their expert and they would have done so in either this trial or the previous trials; it doesn't have to be the same expert. Pernix doesn't say that, neither does Abstracts. In fact, I think in that Abstracts case we cited it was a different expert and that discovery was allowed. So the notion that it has to be the same expert, that's just wrona.

And then finally on the last point, the hearsay point, you know that's incorrect, too. It's incorrect that an expert in one field can't rely upon the testimony or the statements or the opinions of someone else in another field. That's what people do when they rely upon publications or

1 respect to the first request.

Let's move on to the second request.

3 MR. WALTER: Thank you, Your Honor.

4 The second request, I believe you -- the Natera

5 sales data, that's the one I'm going to take next.

6 I'll just stick to the arguments here. The 7 first thing they do is they complain that there's no 8 document request that relevant to this. That was a 9 surprising argument for us to see in this brief because it 10 was not once mentioned during meet and confer. If they 11 really thought that the lack of a document request was a

12 barrier here, they should have said so and we could have 13 remedied. So I think they've waived that argument. But

14 what's also really telling here is they don't submit the

15 document request we have in this case. And if you look at

16 the document request, which are not before the Court, I can

17 only tell you what's there, I think we probably do have

18 document requests, Request 20 asks for documents relating to

19 identifying somatic sensations. Request 31 asks for things

20 related to the accused product. And to the extent that's

21 sold as a unit, that would be an accused products. Request

22 42 asks for the same sort of things. So the lack of

23 document request was kind of a strange and surprising 24

argument.

25 Also, they make an argument based on the merits.

	Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 695 of 739 PageID
1	30 #: 1 3445 at 10:38 a.m.)
2	I hereby certify the foregoing is a true
3	and accurate transcript from my stenographic notes in the
4	proceeding.
5	/s/ Michele L. Rolfe, RPR, CRR
	U.S. District Court
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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

	CORPORATION OF)	
AMERICA HOLD	INGS,)	
	Plaintiff,)	C.A. No. 21-669 (GBW)
V.)	
NATERA, INC.)	
	Defendant.		
LABORATORY C AMERICA HOLD	CORPORATION OF INGS,))	
	Plaintiff,)	C.A. No. 21-1635 (GBW)
V.)	
NATERA, INC.)	
	Defendant.)	

PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION IN LIMINE NO. 2:

PRECLUDE PLAINTIFF FROM USING, OR PRESENTING EVIDENCE OR

ARGUMENT REGARDING, THE TESTIMONY AND

EXPERT REPORTS OF RYAN SULLIVAN

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Dated: August 6, 2025

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Attorneys for Plaintiff Laboratory Corporation of America Holdings Natera's attempt to exclude Ryan Sullivan's materials rests upon little more than a misunderstanding of law and a mischaracterization of facts. Regarding the law, Natera's lead case, *Pernix*, is not nearly as authoritative as Natera contends. Judge Bryson begins his analysis of the admissibility of prior expert testimony by explaining that "case law on this subject is mixed, however, *with courts reaching different results under a variety of different factual circumstances.*" *Pernix Ireland Pain Dac v. Alvogen Malta Operations Ltd.*, 316 F. Supp. 3d 816, 819 (D. Del. 2018) (emphasis added). In other words, the law calls for a fact-specific inquiry.

Unfortunately for Natera, the facts here, too, are not as it represents. First, Alexander Clemons, Labcorp's damages expert, cited Dr. Sullivan's materials from the *ArcherDX* Case in his opening report, served on *June 16, 2023*. If Natera found this objectionable, it should have said so *eight months* before raising the issue. Second, Nisha Mody, Natera's damages expert in this case, cites testimony from *James Malackowski* in her July 21, 2023 report. Mr. Malackowski, of course, was Dr. Sullivan's counterpart in the *ArcherDX* Case – namely, *ArcherDX's damages expert*. Natera's brief makes no mention of this reciprocal usage. For all of the reasons above, Natera's motion should be denied.

I. DR. SULLIVAN'S MATERIALS ARE ADMISSIBLE

Under Rule 703, an expert may provide an opinion based on inadmissible evidence as long as it is of the type reasonably relied on by experts in the field—such as the testimony of other experts. See, e.g., Hayes v. Raytheon Co., 808 F.Supp.1326, 1329 (N.D. Ill. 1992); Wilbern v. Culver Franchising System, Inc., No. 13-cv-3269, 2015 WL 5722825, at *14 (N.D. Ill. Sept. 29, 2015) ("In general, however, Rule 703 permits an expert to rely on the opinions of other experts in a related field."); Kovary v. Honeywell Int'l, Inc., No. 10-cv-494-GW(CWX), 2014 WL 12564090, at *4 (C.D. Cal. Mar. 17, 2014) ("Experts are permitted to rely on hearsay, including

the opinions of other experts, if proper foundation is laid that others in the field would likewise rely on them.").

Importantly, Rule 703 expressly allows an expert to disclose the inadmissible statements he or she relied on to the jury if its probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect. FRE 703 (The "proponent of the opinion may disclose [inadmissible hearsay statements] to the jury only if their probative value in helping the jury evaluate the opinion substantially outweighs their prejudicial effect."); *see also Hayes v. Raytheon Co.*, 808 F.Supp. at 1329 ("Rule 703 liberalizes the admissibility of expert testimony by permitting experts to base their opinions on hearsay and other evidence not admissible in court."); *Paddack v. Dave Christensen, Inc.*, 745 F.2d 1254, 1261–62 (9th Cir. 1984) (noting that FRE 703 permits "hearsay, or other inadmissible evidence, upon which an expert properly relies, to be admitted to explain the basis of the expert's opinion.").

Here, both parties have proceeded in accordance with these principles. Natera produced Dr. Sullivan's materials, in his capacity as Natera's damages expert in the *ArcherDX* Case, to Labcorp, and Labcorp's damages expert Mr. Clemons duly relied upon them in formulating his report. *See, e.g.*, Ex. A. Natera then proceeded to request Mr. Malackowski's materials, in *his* capacity as *ArcherDX*'s damages expert in the *ArcherDX* Case, to Natera. Ex. B at 29:10-16. Natera's damages expert, Dr. Mody, then duly relied upon *Mr. Malackowski's* materials in formulating *her* report. *See, e.g.*, Ex. C ¶ 198. In summary, both sets of damages expert materials from the *ArcherDX* Case were produced, and both parties' current damages experts have relied upon the opposite party's damages expert materials from the *ArcherDX* Case in formulating their current opinions. The parties could not have proceeded in a more reciprocal fashion.

Indeed, from the outset, Natera represented to Labcorp that it viewed the Sullivan and Malackowski reports as equivalent and corresponding, and stated that their use ought to go together. *See*, *e.g.*, D.I. 187 at 3. Invitae readily agreed to their reciprocal use. *Id.* If Natera is now experiencing buyer's remorse over its approach to production and usage of the Sullivan and Malackowski materials, that is hardly Labcorp's fault.

II. NATERA WAIVED ANY OBJECTIONS TO DR. SULLIVAN'S MATERIALS

In addition to the above, Natera has also waived, at multiple points, its rights to object to Labcorp's usage of Dr. Sullivan's materials.

First, as described above, from the very beginning, both parties understood the production and use of damages expert materials from the *ArcherDX* Case to be reciprocal in nature and made such representations to each other and the Court. Both parties then proceeded to use said materials in the exact same way—namely, by relying upon them in their damages expert reports. If Natera, upon receiving Mr. Clemons' report on June 16, 2023, believed Labcorp's usage of such to be improper, Natera should have said so. Instead, *over a month later*, Natera served Dr. Mody's rebuttal report, in which Dr. Mody did the exact same thing as Mr. Clemons—rely upon the opposing party's damages expert materials from the *ArcherDX* Case. If Natera no longer feels the need for Mr. Malackowski's materials, it does not need to present them, but it cannot now force Labcorp to divest its own expert reports of Dr. Sullivan's materials.

Second, and relatedly, Natera has been in possession of Mr. Clemons' opening report for *eight months* prior to serving the present motion *in limine*. If Natera had an issue with evidence Mr. Clemons relied upon and sought to present, it should have moved to strike in a timely fashion, not delay until the eve of trial.

August 6, 2025

Respectfully submitted,

FARNAN LLP

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CERTIFICATE OF SERVICE

I, Brian E. Farnan, hereby certify that on August 6, 2025, a copy of PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION *IN LIMINE* NO. 2: PRECLUDE LABCORP FROM USING, OR PRESENTING EVIDENCE OR ARGUMENT REGARDING, THE TESTIMONY AND EXPERT REPORTS OF RYAN SULLIVAN was served on the following as indicated:

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EXHIBIT A



INVITAE CORPORATION

V.

NATERA, INC.

Civil Action Nos. 1:21-cv-00669 & 1:21-cv-01635

United States District Court for the District of Delaware

EXPERT REPORT OF ALEXANDER L. CLEMONS

June 16, 2023

1	FIRI	M BACKGROUND AND QUALIFICATIONS	1			
2	SUM	MARY OF ASSIGNMENT	2			
3	SUM	MARY OF OPINIONS	4			
4	REL	EVANT PARTIES	5			
	4.1	Invitae	5			
	4.2	Natera				
5	THE	PATENTS-IN-SUIT	15			
6	IND	USTRY BACKGROUND	19			
7	THE	ACCUSED PRODUCT	. 24			
8	TIM	ELINE OF EVENTS	. 26			
9	LOS	T PROFITS COMPENSATION	. 29			
	9.1	DEMAND FOR THE PATENTED PRODUCT	. 30			
	9.2	ABSENCE OF ACCEPTABLE NON-INFRINGING ALTERNATIVES	. 32			
	9.3	SUFFICIENT CAPACITY	. 37			
	9.4	QUANTIFICATION	. 38			
10	REA	REASONABLE ROYALTY COMPENSATION43				
	10.1	Overview	. 43			
	10.2	HYPOTHETICAL VS. REAL WORLD NEGOTIATIONS				
	10.3	NATURE OF RIGHTS BEING LICENSED				
	10.4	SUMMARY OF APPROACH				
	10.5	COMPENSATION PERIOD AND ACCUSED PRODUCTS				
	10.6	HYPOTHETICAL NEGOTIATION DATE				
	10.7	PARTIES TO THE NEGOTIATION	. 47			
11	THE MARKET, INCOME, AND COST APPROACHES47					
	11.1	THE MARKET APPROACH				
	11.2	THE INCOME APPROACH				
	11.3	THE COST APPROACH	. 73			
12	GEC	PRGIA-PACIFIC FACTOR ANALYSIS	. 74			
	12.1	FACTOR #1: THE ROYALTIES RECEIVED BY THE PATENTEE FOR THE LICENSING OF THE PATENT-IN-SUIT PROVING OR TENDING TO PROVE AN ESTABLISHED ROYALTY	_			
	12.2	FACTOR #2: THE RATES PAID BY THE LICENSEE FOR THE USE OF OTHER PATENTS COMPARABLE TO THE				
		PATENT-IN-SUIT.	. 75			
	12.3	FACTOR #3: THE NATURE AND SCOPE OF THE LICENSE, AS EXCLUSIVE OR NON-EXCLUSIVE; OR AS RESTRICTED OR NON-RESTRICTED IN TERMS OF TERRITORY OR WITH RESPECT TO WHOM THE				
		MANUFACTURED PRODUCT MAY BE SOLD	75			

	12.4	FACTOR #4: THE LICENSOR'S ESTABLISHED POLICY AND MARKETING PROGRAM TO MAINTAIN HIS PATENT MONOPOLY BY NOT LICENSING OTHERS TO USE THE INVENTION OR BY GRANTING LICENSES UNDER
		SPECIAL CONDITIONS DESIGNED TO PRESERVE THAT MONOPOLY
	12.5	FACTOR #5: THE COMMERCIAL RELATIONSHIP BETWEEN THE LICENSOR AND LICENSEE, SUCH AS,
		WHETHER THEY ARE COMPETITORS IN THE SAME TERRITORY IN THE SAME LINE OF BUSINESS; OR WHETHER THEY ARE INVENTOR AND PROMOTER
	12.6	FACTOR #6: THE EFFECT OF SELLING THE PATENTED SPECIALTY IN PROMOTING SALES OF OTHER
		PRODUCTS OF THE LICENSEE; THE EXISTING VALUE OF THE INVENTION TO LICENSOR AS A GENERATOR
		OF SALES OF HIS NON-PATENTED ITEMS; AND THE EXTENT OF SUCH DERIVATIVE OR CONVOYED SALES.
	12.7	FACTOR #7: THE DURATION OF THE PATENT AND THE TERM OF THE LICENSE
	12.8	FACTOR #8: THE ESTABLISHED PROFITABILITY OF THE PRODUCT MADE UNDER THE PATENT; ITS COMMERCIAL SUCCESS; AND ITS CURRENT POPULARITY
	12.9	FACTOR #9: THE UTILITY AND ADVANTAGES OF THE PATENTED PROPERTY OVER OLD MODES OR
		DEVICES, IF ANY, THAT HAD BEEN USED FOR WORKING OUT SIMILAR RESULTS
	12.10	FACTOR #10: THE NATURE OF THE PATENTED INVENTION; THE CHARACTER OF THE COMMERCIAL
		EMBODIMENT OF IT AS OWNED AND PRODUCED BY THE LICENSOR; AND THE BENEFITS TO THOSE WHO HAVE USED THE INVENTION
	12.11	FACTOR #11: THE EXTENT TO WHICH THE INFRINGER HAS MADE USE OF THE INVENTION; AND ANY EVIDENCE PROBATIVE OF THE VALUE OF THAT USE
	12.12	FACTOR #12: THE PORTION OF THE PROFIT OR THE SELLING PRICE THAT MAY BE CUSTOMARY IN THE
		PARTICULAR BUSINESS OR IN COMPARABLE BUSINESSES TO ALLOW FOR THE USE OF THE INVENTION OR ANALOGOUS INVENTIONS
	12.13	FACTOR #13: THE PORTION OF THE REALIZABLE PROFIT THAT SHOULD BE CREDITED TO THE INVENTION
		AS DISTINGUISHED FROM NON-PATENTED ELEMENTS, THE MANUFACTURING PROCESS, BUSINESS RISKS,
		OR SIGNIFICANT FEATURES OR IMPROVEMENTS ADDED BY THE INFRINGER
	12.14	FACTOR #14: THE OPINION TESTIMONY OF QUALIFIED EXPERTS
	12.15	FACTOR #15: THE ROYALTY THAT A LICENSOR (SUCH AS THE PATENTEE) AND A LICENSEE (SUCH AS THE
		INFRINGER) WOULD HAVE AGREED UPON IF BOTH HAD BEEN REASONABLY AND VOLUNTARILY TRYING
		TO REACH AN AGREEMENT; THAT IS, THE AMOUNT WHICH A PRUDENT LICENSEE – WHO DESIRED, AS A
		BUSINESS PROPOSITION, TO OBTAIN A LICENSE TO MANUFACTURE AND SELL A PARTICULAR ARTICLE
		EMBODYING THE PATENTED INVENTION – WOULD HAVE BEEN WILLING TO PAY AS A ROYALTY AND YET
		BE ABLE TO MAKE A REASONABLE PROFIT AND WHICH AMOUNT WOULD HAVE BEEN ACCEPTABLE BY A
		PRUDENT PATENTEE WHO WAS WILLING TO GRANT A LICENSE
13	DET	ERMINATION OF REASONABLE ROYALTY DAMAGES98
14	PREJ	UDGMENT INTEREST
15	CON	CLUSION
16	SIGN	IATURE102

1 FIRM BACKGROUND AND QUALIFICATIONS

My name is Alexander L. Clemons, and I am a Managing Director at Ocean Tomo, LLC, a part of J.S. Held. Ocean Tomo provides Financial Expert, Management Consulting, and Advisory services related to intellectual property ("IP") and other intangible assets, corporate accounting investigations, regulatory and reporting obligations, solvency and restructuring, and contractual or competition disputes. Practice offerings address economic damage calculations and testimony, accounting investigations and financial forensics, technology and intangible asset valuation, strategy and risk management consulting, mergers and acquisitions, debt and equity private placement, and IP brokerage. Subsidiaries of Ocean Tomo include Ocean Tomo Investments Group, LLC, a registered broker dealer. With more than 100 offices globally, J.S. Held assists clients—corporations, insurers, law firms, governments, and institutional investors—on complex technical, scientific, and financial matters across all assets and value at risk.

I work in Ocean Tomo's Intellectual Property Disputes Financial Expert Testimony practice. This practice area quantifies economic damages arising from intellectual property disputes and provides general litigation support. I have extensive experience related to the assessment of economic damages in litigation matters involving intellectual property, breach of contract, and other claims. Outside of a litigation context, I have experience with intellectual property valuation and have provided analytical support to clients engaged in licensing negotiations and other transactions.

I have assisted clients in numerous engagements involving the valuation of intellectual property and the determination of economic damages in commercial suits, including patent infringement, trademark infringement, copyright infringement, trade secret misappropriation, technology misappropriation, and breach of contract litigation. I possess a solid understanding of the financial issues and theories related to the quantification of damages in litigation. While specific issues vary by engagement, most have included evaluation and analysis of financial and strategic data to support or rebut quantification of lost profits, reasonable royalties, price erosion, unjust enrichment, commercial success, and/or business valuation. Various engagements have also included analysis of issues such as of Hatch Waxman Act market exclusivity, business significance of licensing terms including RAND obligations, and equities of a potential injunction. I have supported counsel in all phases of the litigation process from discovery to trial, and my experience spans a wide variety of industries including pharmaceuticals, medical devices, medical diagnostics, laboratory instruments and reagents, healthcare services, healthcare data, telecommunications, semiconductors, consumer electronics, smart phones, software, gaming, VR/AR, e-commerce, consumer goods, food products, dietary supplements, chemical products, automotive, entertainment, financial services, insurance, firearms, military and aviation technologies, airport security, and ventilation products, among others.

In addition to my role at Ocean Tomo, I have participated in and supported the advanced trial advocacy program at the Notre Dame Law School as a mock expert witness. I am a registered attorney licensed to practice law in the State of Illinois. I graduated with Academic Excellence from the University of Illinois, Urbana-Champaign, with an MBA concentrated in Finance. I graduated cum laude from DePaul University, College of Law, with a JD. I also hold a Bachelor of Arts in Rhetoric from the University of Illinois, Urbana-Champaign.

Page 708 of 739 PageID

royalties, in addition to or as an alternative to lost profits, I have analyzed quantitative and qualitative valuation metrics, including the Georgia-Pacific factors, and have reached a conclusion regarding the appropriate reasonable royalties due to Invitae for Natera's use of the Patents-in-Suit in connection with the Accused Product. As summarized in the figure below, I have calculated total damages, both including and excluding lost profits.

3/31 - 12/31 2020 Lost Profits, High Reasonable Royalty Damages, High LP Total Damages, High LP 3/31 - 12/31 2020 Lost Profits, Low Reasonable Royalty Damages, Low LP Total Damages, Low LP 3/31 - 12/31 2020 Total Total Damages, Royalty Only

Figure 26: Summary of Damages through 2022⁵¹¹

I reserve the right to update my damages calculations if updated sales information is provided.

16 **SIGNATURE**

Respectfully submitted,

Case 1:21-cv-01635-GBW

alemba L. Clemove June 16, 2023 Alexander L. Clemons Date

511 Appendix 3.1.

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Appendix 2.2

Depositions and Associated Exhibits

Mr. David Bassette, February 9, 2023

Mr. Gregroy Porreca, April 28, 2023

Ms. Hila Moyal, May 17, 2023

Mr. Jim Stuart, April 6, 2023

Mr. John Fesko, May 26, 2023

Mr. Kevin Masukawa, February 28, 2023

Ms. Mary Freivogel, February 24, 2023

Mr. Nirav Malani, March 28, 2023

Mr. Richard Lusk, June 9, 2023

Mr. Solomon Moshkevich, May 23, 2023

Expert Reports

Expert Report of Dan E. Krane, June 16, 2023

Legal Filings and Pleadings

Complaint, Case No. 1:21-cv-00669, May 7, 2021

Complaint, Case No. 1:21-cv-01635, November 21, 2021

Invitae Corporation's First Set of Interrogatories to Natera, Inc. (Nos. 1-5), February 15, 2022

Invitae Corporation's First Supplemental Responses and Objections to Natera, Inc.'s First Set of Interrogatories (Nos. 3 and 7), September 20, 2022

Invitae Corporation's First Supplemental Responses and Objections to Natera, Inc.'s Third Set of Interrogatories (Nos. 10-12), January 18, 2022

Invitae Corporation's First Supplemental Responses and Objections to Natera, Inc.'s Third Set of Interrogatories (Nos. 10-12), January 18, 2023

Invitae Corporation's Responses and Objections to Natera, Inc.'s Fifth Set of Interrogatories (Nos. 16-25), March 3, 2023

Invitae Corporation's Responses and Objections to Natera, Inc.'s First Set of Interrogatories (Nos. 1-8), March 25, 2022

Invitae Corporation's Responses and Objections to Natera, Inc.'s Fourth Set of Interrogatories (Nos. 14-15), February 13, 2023

Invitae Corporation's Responses and Objections to Natera, Inc.'s Second Set of Interrogatories (No. 9), June 21, 2022

Invitae Corporation's Responses and Objections to Natera, Inc.'s Third Set of Interrogatories (Nos. 10-13), December 1, 2022

Invitae Corporation's Second Set of Interrogatories to Natera, Inc. (Nos. 6-15), January 16, 2023

Invitae Corporation's Second Supplemental Responses and Objections to Natera, Inc.'s First Set of Interrogatories (Nos. 3 and 7), September 23, 2022

Invitae Corporation's Supplemental Responses and Objections to Natera, Inc.'s Fifth Set of Interrogatories (Nos. 16-25), April 28, 2023

Invitae Corporation's Supplemental Responses and Objections to Natera, Inc.'s Fifth Set of Interrogatories (Nos. 17-22), June 5, 2023

Invitae Corporation's Supplemental Responses and Objections to Natera, Inc.'s First Set of Interrogatories (Nos. 1 and 5), June 5, 2023

Invitae Corporation's Supplemental Responses and Objections to Natera, Inc.'s First Set of Interrogatories (Nos. 1-8), April 28, 2023

Invitae Corporation's Supplemental Responses and Objections to Natera, Inc.'s First Set of Interrogatories (Nos. 2 and 7), February 15, 2023

Invitae Corporation's Supplemental Responses and Objections to Natera, Inc.'s Fourth Set of Interrogatories (Nos. 14-15), April 28, 2023

Invitae Corporation's Supplemental Responses and Objections to Natera, Inc.'s Interrogatories (No. 15), March 24, 2023

Invitae Corporation's Supplemental Responses and Objections to Natera, Inc.'s Second Set of Interrogatories (No. 9), April 28, 2023

Invitae Corporation's Supplemental Responses and Objections to Natera, Inc.'s Third Set of Interrogatories (Nos. 10-13), April 28, 2023

Invitae Corporation's Third Set of Interrogatories to Natera, Inc. (Nos. 16-25), February 1, 2023

Invitae Corporation's Third Supplemental Responses and Objections to Natera, Inc.'s First Set of Interrogatories (No. 3), September 30, 2022

Memorandum Opinion, October 18, 2022

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Legal Filings and Pleadings (continued)

Natera, Inc.'s Fifth Set of Interrogatories to Invitae Corporation, (Nos. 16-25), February 1, 2023

Natera, Inc.'s First Set of Interrogatories to Invitae Corporation, (Nos. 1-7), February 23, 2022

Natera, Inc.'s Fourth Set of Interrogatories to Invitae Corporation, (Nos. 14-15), January 12, 2023

Natera, Inc.'s Responses and Objections to Plaintiffs' Notice of Deposition of Natera, Inc. Pursuant to Federal Rule of Civil Procedure 30(b)(6), January 19, 2023

Natera, Inc.'s Responses to Plaintiff's Second Set of Interrogatories (Nos. 6-15), February 15, 2023

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Natera, Inc.'s First Supplemental Responses to Invitae's Second Set of Interrogatories (Nos. 6-7, 11), May 19, 2023

Natera's First Supplemental Response and Objections to Invitae's Interrogatory Nos. 2, 4, December 8, 2022

Natera's Objections and Responses to Plaintiff's First Set of Interrogatories (Nos. 1-5), March 17, 2022

Natera's Supplemental Objections and Response to Plaintiff's Interrogatory Nos. 3 & 4, February 15, 2023

Natera's Third Supplemental Responses and Objections to Invitae's First Set of Interrogatories (Nos. 2-5), May 19, 2023

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U.S. Patent No. 9,816,137

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Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 714 of 739 PageID

EXHIBIT B

Case 1:2	1-cv-01635-GBW	Document 302-1 #: 134	Filed 08/27/25 165	5 Page 715 of 739 PageID
1		IN THE UN	IITED STATES	DISTRICT COURT
2	IN AND FOR THE DISTRICT OF DELAWARE			ICT OF DELAWARE
3			,	
4	INVITAE CORPOR	RATION,)	Civil Action Nos.
5		tiff,)	21-cv-669-GBW and 21-cv-1635-GBW
6	v.)	21-CV-1633-GBW
7	NATERA, INC.,)	
8		Defendant.		
9				
10				
11	Wilmington, Delaware Friday, July 21, 2023			
12		Tele	econference 1	Transcript
13		-		
14		ORABLE GREGORY TED STATES DIS		
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25			Michel	le L. Rolfe, RPR, CRR

Case 1:2	l-cv-01635-GBW	Document 302-1 Filed 08/27/25 Page 716 of 739 PageID #: 13466 2
		_
1	APPEARANCES:	
2		ENDNAN TID
3		FARNAN, LLP BY: MICHAEL J. FARNAN, ESQ.
4		-and-
5		WEIL GOTSHAL & MANGES, LLP BY: DEREK WALTER, ESQ.
6		Counsel on behalf of Invitae Corporation
7		
8		MORRIS NICHOLS ARSHT & TUNNELL, LLP BY: DEREK JAMES FAHNESTOCK, ESQ.
9		-and-
10		
11		GROOMBRIDGE WU BY: ELIZA P. STRONG, ESQ. ERIC ALAN STONE, ESQ.
12		
13		Counsel for Natera, Inc.
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them, in that they are entitled to this Brophy transcript, even though they didn't depose him, and they are entitled to the Moshkevich and Fesko transcript, even though they didn't depose them. And, you know, it seems to me that what they are looking for here is improper with respect to Mr. Brophy, they could have deposed him. And what they are looking to do with the Fesko and Moshkevich testimony is give them more hours than what the rule would apply by deposing them here, deposing them there and using all of it and I respectfully submit that that's inappropriate.

Thank you, Your Honor.

MR. WALTER: Your Honor, real quickly, if the rule is going forward I can't have someone else's prior deposition transcript in another cases unless I do a deposition -- and going forward I'm going to make sure I take every possible deposition out of everybody else in every case because I'm not going to ever get any relevant discovery regarding what they might have said; if that's the rule, it would be good to know.

THE COURT: All right. So here on this issue

I'm going to separate Brophy from Fesko and Moshkevich.

With respect to the request for Brophy, it's denied.

With respect to the request of Fesko and Moshkevich, it's granted.

1 MR. WALTER: Thank you, Your Honor. 2 MR. STONE: Thank you. 3 THE COURT: All right. The parties should follow the protective order with respect to this information 4 5 that's being produced. 6 So that's all I have on the agenda for today. 7 MR. STONE: Your Honor, just one thing I want to 8 put on the record, it's in the letter, but I want to make 9 clear. 10 11 12 13 14 15 16 17 And with that, nothing further from Natera and 18 thank you, Your Honor. 19 THE COURT: All right. So Invitae represented 20 that you would produce your damages expert report, so Natera 21 expects to get that. So the Court will expect that to be 22 produced as well. 23 So with that, we'll adjourn. 24 Everybody have a good day. 25 (Whereupon, the following proceeding concluded

Case 1:2	1-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 719 of 739 PageID #: 13469 30
1	at 10:38 a.m.)
2	I hereby certify the foregoing is a true
3	and accurate transcript from my stenographic notes in the
4	proceeding.
5	/s/ Michele L. Rolfe, RPR, CRR U.S. District Court
6	O.S. District Court
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EXHIBIT C

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY



UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

Invitae Corporation

v.

Natera, Inc.

Civil Actions: 1:21-cv-00669 & 1:21-cv-01635

Nisha M. Mody, Ph.D.
July 21, 2023

Table of Contents

l.	Q	ualification	ons, Assignment and Compensation	3
	1.1.	Quali	fications	3
	1.2.	Assig	nment	3
	1.3.	Scop	e of Work	3
	1.4.	Fram	ework	4
2.	Sı	ummary o	of Opinions	5
3.	В	ackgroun	d	8
	3.1.	The I	Parties at Issue	8
		3.1.1.	Invitae	8
		3.1.2.	Natera	9
	3.2.	Mark	etplace Background	10
	3.3.	The I	Patents-in-Suit	15
	3.4.	Accu	sed Technology	16
4.	D	iscussion	of The Expert Report of Alexander Clemons	19
	4.1.	Mr. C	Clemons' Lost Profit Analysis	20
		4.1.1.	Demand for the Patented Product	20
		4.1.2.	Absence of Acceptable Non-infringing Alternatives	28
		4.1.3.	Marketing and Manufacturing Capability to Support Demand	39
		4.1.4.	Quantification of Lost Profits	41
	4.2.	Alter	native Lost Profits Analysis	49
	4.3.	Mr. C	Clemons' Reasonable Royalty Analysis	51
		4.3.1.	Molecular Loop Acquisition-October 12, 2018	
		4.3.2.	Molecular Loop Sale March 13, 2021	55
		4.3.3.	Mr. Clemons' Other Affirmative Analyses: Cost and Income Approaches	58
		4.3.4.	Mr. Clemons' Georgia-Pacific opinions	59
		4.3.5.	Mr. Clemons' Failure to Apportion	62
5.	D	amages A	analysis	67
	5.1.	,	gia-Pacific No. 1: The royalties received by the patent owner for the licensing of the proving or tending to prove an established royalty	
	5.2.		gia-Pacific No. 2: The rates paid by the licensee for the use of other patents compa t-in-suit.	
	5.3.	restri	gia-Pacific No. 3: The nature and scope of the license, as exclusive or non-exclusive ted or non-restricted in terms of territory or with respect to whom the manufacture be sold	ed product
	5.4.	Georgi paten	gia-Pacific No. 4: The licensor's established policy and marketing program to main t monopoly by not licensing others to use the invention or by granting licenses und tions designed to preserve that monopoly	ntain its ler special
	5.5.	whetl	gia-Pacific No. 5: The commercial relationship between the licensor and the licensher they are competitors in the same territory in the same line of business, or wheth tor and promoter.	ner they are

5.6.	<i>Georgia-Pacific</i> No. 6: The effect of selling the patented specialty in promoting sales of other products of the licensee; the existing value of the invention to the licensor as a generator of sales of its non-patented items; and the extent of such derivative or convoyed sales
5.7.	Georgia-Pacific No. 7: The duration of the patent and the term of the license
5.8.	Georgia-Pacific No. 8: The established profitability of the product made under the patent; its commercial success; and its current popularity
5.9.	Georgia-Pacific No. 9: The utility and advantages of the patent property over the old modes or devices, if any, that had been used for working out similar results
5.10.	Georgia-Pacific No. 10: The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention
5.11.	Georgia-Pacific No. 11: The extent to which the infringer has made use of the invention, and any evidence probative of the value of that use
5.12.	Georgia-Pacific No. 12: The portion of the profit or of the selling price that may be customary in the business or in comparable businesses to allow for the use of the invention or analogous inventions.
5.13.	Georgia-Pacific No. 13: The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer
5.14.	Georgia-Pacific No. 14: The opinion testimony of qualified experts
5.15.	Georgia-Pacific No. 15: The amount that a licensor (such as the patent owner) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to reach an agreement; that is, the amount that a prudent licensee – who desired, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention – would have been willing to pay as a royalty and yet be able to make a reasonable profit, and which amount would have been acceptable by a prudent patent owner who was willing to grant a license

1. Qualifications, Assignment and Compensation

1.1. Qualifications

- (1) I am a Managing Director at Intensity LLC, a consulting firm specializing in litigation damages and financial valuation. I work primarily on economic and financial issues that arise from complex litigation, including patent litigation. In December 2019, I co-founded Eurekanomics LLC with my partner, Evan Schulz. Prior to that, I was a partner at OSKR LLC from 2010 to 2019. For some of the time while I was at OSKR, I also co-taught a course on the economics and finance of intellectual property at Santa Clara University School of Law. I have more than twenty years' experience as a consultant and expert of economic analysis.
- I have analyzed numerous issues including damages, valuations, licensing practices, prejudgment interest, economic domestic industry, public interest, irreparable harm, trade secret monetary remedies, competitive markets, and antitrust harm. I continue to give lectures to fellow economists, businesspeople, and attorneys. I provide a list of publications I have authored in my Appendix A. Appendix A also contains my CV and at least the last six years of my testifying experience.

1.2. Assignment

(3) I have been retained by Groombridge, Wu, Baughman and Stone LLP, counsel for Natera, Inc. ("Natera") to consider the opinions of Mr. Alexander L. Clemons provided in his Expert Report dated June 16, 2023 and to offer an alternative rebuttal damages opinion in the event liability is found and Invitae Corporation ("Invitae") is entitled to damages.

1.3. Scope of Work

- (4) Intensity is being compensated at a rate of \$985 per hour for my work on this matter and at lower rates for time spent by others on my team. The compensation of Intensity is not dependent on the substance of my testimony or the outcome of this matter.
- (5) This report is a statement of opinions I currently expect to express in this matter and the bases and reasons for those opinions. In forming the opinions expressed in this report, I relied upon my education, experience, and knowledge of the subjects discussed. I have also considered documents and other materials, which are cited herein and/or listed in Appendix B. I have also relied on discussions with Dr. Michael Metzker and Mr. John Fesko, Mr. David Bessette, Dr. Raheleh Salari, and Dr. Hsin-Ta Wu and I have reviewed the reports of the technical experts, Dr. Michael Metzker, Dr. Dan Edward Krane and Dr. Joshua P. Earl that were provided along with the Expert

5.11. *Georgia-Pacific* No. 11: The extent to which the infringer has made use of the invention, and any evidence probative of the value of that use.

(196)	Dr. Salari explains that
	.393
	. As such, l
	assume Natera has made use of the invention and this would suggest that a rate closer to \$2.33 million or more
	may be appropriate given what has been discussed in this report.

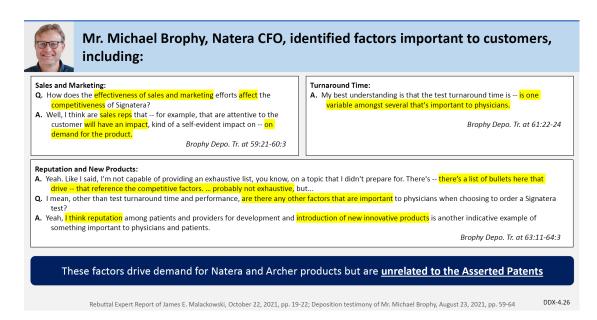
- 5.12. Georgia-Pacific No. 12: The portion of the profit or of the selling price that may be customary in the business or in comparable businesses to allow for the use of the invention or analogous inventions.
- (197) This factor has no effect on the starting royalty as I have seen no relevant information for this factor.
 - 5.13. Georgia-Pacific No. 13: The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.

(198)	I have discussed all of the business risks Natera has incurred by creating a novel product and creating demand f	for
	this novel product and I incorporate those discussions by reference here.	
	:	

."); Expert Report of Michael Metzker, Ph.D.,

June 16, 2023, at 80.

³⁹³ Raheleh Salari, May 2, 2023, Dep. Tr. at 68:9-70:14 ("Q Okay. As of this time in 2017 when you were conceptualizing the workflow, were GATK and Sentieon considered the most accurate variant calling software? MR. STONE: Object to the form. THE WITNESS:



(199)As one can see, non-patent related expenses and risks have been taken by Natera. Natera created the market for MRD testing, and the MRD market exists now because of commercial risks Natera embraced since at least 2019.³⁹⁴ Before Signatera, notes Kevin Masukawa, VP of Oncology Marketing at Natera, .395 To date, 394 Kevin Masukawa, Feb. 28, 2023, Dep. Tr. at 82:11-85:5 ("Q And in your LinkedIn profile, you said you drove adoption of MRD testing in solid tumors to oncologists, surgeons, biopharms. What do you mean -- what did you do to drive the adoption? A Q And do you . Q Why is that? A consider your efforts as successful? A Q When you say you created markets -- (A discussion was held off the written record.) MR. STONE: You may want to withdraw that question and start it again. Q When you said -- what do you mean by "we created a market"? A are you saying Natera also created the market, the MRD market, for Guardant Health? MR. STONE: Object to the form of the question. A l . Q Which year do you think Natera has created this MRD market? A Skevin Masukawa, Feb. 28, 2023, Dep. Tr. at 82:11-84:17 ("Q And in your LinkedIn profile, you said you drove adoption of MRD testing in solid tumors to oncologists, surgeons, biopharms. What do you mean -- what did you do to drive the adoption? A Q And do you consider your efforts as successful? A . Q Why is that? A Q When you say you created markets -(A discussion was held off the written record.) MR. STONE: You may want to withdraw that question and start it again. When you said -- what do you mean by we created a market"? A Q So are you saying Natera also created the market, the MRD market, for Guardant Health? MR. STONE: Object to the form of the question. A Q Which year do you think Natera has created this MRD market? A

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

LABORATORY CORPORATION OF AMERICA HOLDINGS,

Plaintiff,

v.

NATERA, INC.,

Defendant.

C.A. No. 21-cv-669-GBW

C.A. No. 21-cv-1635-GBW

NATERA'S REPLY IN FURTHER SUPPORT OF ITS MOTION TO PRECLUDE LABCORP FROM USING, OR PRESENTING EVIDENCE OR ARGUMENT REGARDING, THE TESTIMONY AND EXPERT REPORTS OF RYAN SULLIVAN

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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Exhibit 20

STONE LLP 565 Fifth Avenue, Suite 2900 New York, NY 10017 (332) 269-0030

Joshua A. Rosefelt GROOMBRIDGE, WU, BAUGHMAN & STONE LLP 801 17th Street, NW, Suite 1050 Washington, DC 20006 (202) 505-5830 Attorneys for Defendant Natera, Inc.

Natera seeks to preclude Labcorp from introducing opinions offered in a different case, *ArcherDX*, by an expert, Ryan Sullivan, Ph.D., who has not been retained and will not testify in this case. Labcorp responds that because 1) its damages expert Mr. Alexander Clemons apparently read some of Dr. Sullivan's prior testimony, *but did not opine about it*, Labcorp has a blank slate to discuss Dr. Sullivan's opinions; and 2) that Natera failed to timely object to the admissibility of Dr. Sullivan's opinions. Labcorp is wrong on both points.

First, Mr. Clemons did not disclose opinions about—or rely on, quote, or even refer to—Dr. Sullivan's testimony. Labcorp rests its entire argument on the fact that Dr. Sullivan's ArcherDX testimony is on Mr. Clemons's "documents considered" list. Opp. at 2 (citing Ex. A). If that matters at all, it cuts against Labcorp: it means Mr. Clemons considered Dr. Sullivan's testimony and then chose not to offer an opinion about it. The inclusion of Dr. Sullivan's ArcherDX testimony on Mr. Clemons's materials considered list does not give Labcorp any basis, much less a blank slate, to introduce and discuss Dr. Sullivan's prior opinions here. Fed. R Civ. P. 26(a)(2) requires that experts testifying under FRE 703 disclose "all opinions the witness will express" 90 days before trial. Mr. Clemons disclosed no opinions about Dr. Sullivan in his reports, and Labcorp points to no passages in the body of Mr. Clemons's reports where he even mentions Dr. Sullivan.

Second, Natera's objection is timely. Natera objected to the admissibility of Dr. Sullivan's testimony and reports in a letter filed with the Court on June 23, 2023, **after** Mr. Clemons's report was served on June 16, 2023. Ex. 1 at 2. ("Dr. Sullivan's materials would not be admissible at trial in this case."). At the parties' July 21, 2023 hearing, the Court deferred ruling on the admissibility of Dr. Sullivan's opinions. Ex. 2 12:22–13:2 ("whether or not it's admissible is another question."). Natera's timely motion appropriately re-raises this admissibility question.

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

INVITAE CORPORATION,)
Plaintiff	;,))
V.) C.A. No. 21-669 (GBW)
NATERA, INC.,) HIGHLY CONFIDENTIAL :) FILED UNDER SEAL
Defenda	ant.)
INVITAE CORPORATION,)
Plaintiff) :,)
v.) C.A. No. 21-1635 (GBW)
NATERA, INC.,)
Defenda	ant.)

LETTER TO THE HONORABLE GREGORY B. WILLIAMS FROM **DEREK J. FAHNESTOCK REGARDING DISCOVERY DISPUTE**

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Karen Jacobs (#2881) Brian P. Egan (#6227) Derek J. Fahnestock (#4705) 1201 North Market Street

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Attorneys for Defendant Natera, Inc.

OF COUNSEL:

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Dear Judge Williams:

Natera respectfully submits this answering letter regarding the pending discovery dispute.

Natera's Position Regarding Production of Altera Sales Data

Invitae first sought "financials relating to sales of" Natera's Altera product (which is not accused of infringement in this case) in an email on May 5, 2023. Invitae has never served any formal discovery request for these data, which should be reason alone to deny Invitae's request. Worse, Invitae's only basis for seeking this information is its mischaracterization of the February 9, 2023 deposition of David Bessette, Natera's Vice President of Finance. Although Invitae says Mr. Bessette testified that part of the president of Finance and Taylor and the president of Finance and Taylor and

Natera's Position Regarding ArcherDX Materials

Natera recognizes that the Court is presiding over the *ArcherDX* action between Natera and Invitae. But that is a separate lawsuit, and Natera's lead counsel in this case does not represent Natera in that case and is not under the Protective Order in that case. Invitae's request for *ArcherDX* materials should be denied even without regard to the specific materials themselves.

First, the *ArcherDX* materials Invitae seeks were designated as Highly Confidential—Attorney's Eyes' Only pursuant to the Protective Order in that case. *See* C.A. No. 12-125, D.I. 69 (Exhibit B). That Order prohibits the use of such materials for any purpose other than to litigate *that case*. *Id.* at Section 7.1.

The above-captioned actions were filed well after the commencement of the *ArcherDX* case, but there is no cross-use provision in the Protective Order negotiated and entered for this case authorizing the use of information obtained in the *ArcherDX* case, *see* C.A. No. 21-669, D.I. 46, and neither party argued for the consolidation of these cases with the *ArcherDX* case. If Invitae had wanted to treat the cases as the same, it had every opportunity to propose that at the outset to avoid duplicative discovery. Instead, Invitae and its counsel apparently *want* duplicative discovery, to have multiple bites at the apple. That is unfair.

Another issue stemming from the separateness of the actions is that, while counsel for the various Invitae entities (which includes ArcherDX) is the same, Natera's lead counsel here is not involved in the *ArcherDX* litigation. Invitae's counsel should not be using in this litigation the confidential information it obtained in the *ArcherDX* litigation under the terms of the protective order in that case. Yet, Invitae is using the contents of those confidential materials from *ArcherDX* in *this case* to argue why they are relevant and discoverable in the present motion. Moreover, Natera's lead counsel here cannot view in this case the information designated by the Invitae

entities as confidential in the ArcherDX case. Invitae would thus be getting disproportionate discovery if its motion were granted—the ability to see, use, and understand the full context of materials while Natera's lead counsel here would only have access to the portions of those materials that do not contain ArcherDX's confidential information.

Dr. Sullivan's Materials from *ArcherDX*. Invitae's request for Dr. Sullivan's materials is an attempt to circumvent the Court's previous order denying Invitae's motion to compel production of certain agreements involving Natera. See D.I. 177. Invitae protests that it does not seek the "exhibits" to Dr. Sullivan's materials that overlap with the subject matter of its previous, unsuccessful motion to compel, but Dr. Sullivan's reports and deposition testimony in the ArcherDX case refer to the materials as to which this Court denied Invitae's prior request. Invitae merely seeks to gain in a different form the discovery this Court already denied.

Moreover, Dr. Sullivan's materials would not be admissible at trial in this case. He is not an expert in this case and will not be testifying at trial. Although Invitae relies on the *Pernix* case (attached as Exhibit C) to demonstrate why its motion should succeed, Pernix actually proves the opposite—that this discovery is not reasonably calculated to lead to the discovery of admissible evidence (a burden of showing that Invitae bears but fails to address in its motion). As discussed below, these materials themselves are not admissible, and fact discovery is closed, so they cannot "lead" to the discovery of admissible evidence. AgroFresh Inc. v. Essentiv LLC, C.A. No. 16-662-MN-SRF, 2018 WL 9578196, at *2 (D. Del. Dec. 11, 2018) ("To achieve the policy goals of both Rule 26 and Rule 408, courts within the Third Circuit require the moving party to make a 'particularized showing' that the evidence sought is relevant and reasonably calculated to lead to the discovery of admissible evidence.").

Pernix makes clear that an expert's reports or opinions cannot be deemed the statements of a party's agent or employee within the meaning of Fed. R. Evid. 801(d)(2)(C) or (D). Pernix Ireland v. Alvogen, 316 F. Supp. 3d 816, 819-23 (D. Del. 2018); see also Kirk v. Raymark Indus., Inc., 61 F.3d 147, 164 (3d Cir. 1995); VM Techs., LLC v. Intel Corp., C. A. No. 15-33-RGA, 2017 WL 1753999, at *2 (D. Del. May 1, 2017) (report of expert not called to testify was inadmissible hearsay). Dr. Sullivan's opinions and testimony in ArcherDX cannot be admissible in this case as the statements of a Natera agent or employee.

Pernix also provides a roadmap, which Invitae ignores, for when an expert's prior opinions may be deemed the adoptive admissions of a party under Fed. R. Evid. 801(d)(2)(B). Specifically, the opinions of an expert retained by a party in a previous case may be deemed adoptive admissions when the party calls the expert to give testimony to prove a particular fact. 316 F. Supp. at 825. But, as *Pernix* makes clear, the expert's report itself is not evidence of a party's adoption of those opinions. See Pernix, 316 F. Supp. at 825-26. Invitae has made no effort to identify which portions of Dr. Sullivan's prior reports and deposition testimony would bear indicia of having been adopted by Natera based on Dr. Sullivan's later trial testimony in ArcherDX. Invitae's request thus seeks discovery that would not lead to admissible evidence as a matter of law.

To the extent Invitae suggests that Dr. Sullivan's prior reports or deposition testimony could be used to impeach a different expert in this case, *Pernix* also answers that question in the #: 13484

negative: "[I]f statements by a declarant are inadmissible as hearsay, those statements cannot be used to cross-examine a different witness at trial." Id. at 826.

John Fesko and Solomon Moshkevich's Deposition Transcripts and Exhibits from ArcherDX. Invitae first requested these materials in March 2023. After Invitae made that request, Invitae deposed Messrs. Fesko and Moshkevich in this case, in their individual capacities and as Rule 30(b)(6) witnesses. It had a full and fair opportunity to cover any legitimate subject matter.

Invitae's motion makes no effort to explain what non-duplicative information in their ArcherDX depositions would be relevant here and could not have been obtained in their depositions in this case. Invitae has failed to carry its burden to show that the requested information is relevant to "either the claims, defenses, or the subject matter of the litigation" or why its probative value outweighs the costs and burdens producing it would impose on Natera. See Inventio, 662 F. Supp. 2d at 380-81 (noting "[a]lthough the scope of discovery is broad, it is not unlimited"); see also INVISTA N. Am. S.à.r.l. v. M&G USA Corp., C.A. No. 11-1007-SLR-CJB, 2013 WL 12171721, at *2 (D. Del. June 25, 2013).

Michael Brophy's Deposition Transcript and Exhibits from ArcherDX. Natera has not identified Mr. Brophy as a witness in this case and will not be calling him to trial. If Invitae wanted to seek his testimony in this case, it should have noticed his deposition. It chose not to do so. It is hard to imagine anything Mr. Brophy might know that Invitae did not cover in its 56 requests for production, 25 interrogatories, 24 requests for admission, and nine deposition notices under Rules 30(b)(1) and 30(b)(6), but if it needed Mr. Brophy, too, it could have sought his deposition. The ArcherDX case is not a de facto expansion of the deposition limitations and discovery taken in this case. Invitae's only argument now is that Mr. Brophy is a Natera employee who testified about Signatera and PCM in the ArcherDX case. That explains why Invitae might have wanted to depose him, not why it should get to use in this case his deposition from the ArcherDX case. That falls well short of demonstrating that the requested information is relevant to the claims.

Respectfully,

/s/ Derek J. Fahnestock

Derek J. Fahnestock (#4705)

DJF/rah **Enclosures**

cc: All Counsel of Record (via electronic mail)

EXHIBIT 2

1

1	IN THE UNITED STATES DISTRICT COURT
2	IN AND FOR THE DISTRICT OF DELAWARE
3)
4	INVITAE CORPORATION,)
5) Civil Action Nos. Plaintiff,) 21-cv-669-GBW and
6	v.) 21-cv-1635-GBW)
7	NATERA, INC.,)
8	Defendant.
9	
10	
11	Wilmington, Delaware Friday, July 21, 2023
12	Teleconference Transcript
13	
14	BEFORE: HONORABLE GREGORY B. WILLIAMS UNITED STATES DISTRICT COURT JUDGE
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25	Michele L. Rolfe, RPR, CRR

Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 737 of 739 PageID 3487 APPEARANCES: 1 MR. WALTER: Good morning, Your Honor. This is 2 FARNAN, LLP 2 Derek Walter. I'll start out with that issue, as you BY: MICHAEL J. FARNAN, ESQ. 3 3 requested. 4 There's, I think, a key point that needs to be WEIL GOTSHAL & MANGES, LLP BY: DEREK WALTER, ESQ. 5 5 stated upfront that might have been implicit in the brief, Counsel on behalf of Invitae Corporation 6 but might not have been explicit. As the Court knows, we 7 just completed a trial between Invitae and Natera, and the 7 MORRIS NICHOLS ARSHT & TUNNELL, LLP 8 BY: DEREK JAMES FAHNESTOCK, ESQ. Court might recall that in that trial Natera relied upon the 8 9 -and-9 Archer Beacon Dixon agreement through its expert to procure 10 GROOMBRIDGE WU damages, and particularly argued that this agreement 10 ELIZA P. STRONG, ESQ. 11 ERIC ALAN STONE, ESQ. 11 warranted a 20 percent royalty for cancer testing products. 12 Counsel for Natera, Inc. 12 Well, it is fair play and the key point that the Court 13 13 should understand is that our expert is now relying upon 14 that very license to seek damages from Natera. The same 14 15 15 license that Natera previously relied upon to seek damages 16 with respect to Invitae. And that's why this material is 16 17 17 highly relevant. 18 18 If that wasn't clear from the papers, it should 19 19 be clear now. We're relying upon that same agreement that 20 20 they relied upon, that's why this discovery is relevant. 21 21 Let me go through the arguments they raised. 22 The first argument that they raised is that Natera's lead 22 23 23 counsel is not under the protective order from that prior 24 24 litigation. And that argument, frankly, is a strange 25 25 argument. Of course, they concede Natera's confidential 5

1 2 PROCEEDINGS 3 (REPORTER'S NOTE: The following teleconference was held beginning at 10:00 a.m.) THE COURT: Good morning. We're here for a discovery conference in Invitae Corp versus Natera Corp. 6 Civil Action Nos. 21-669 and 21-16345 7 Let's start by having counsel put appearances on 8 9 the record. MR. FARNAN: Good morning, Your Honor. Brian 10 Farnan on behalf of the plaintiff. And with me is Derek 12 Walter from Weil Gotshal. 13 THE COURT: All right. Good morning. 14 Defendants? 15 MS. JACOBS: Good morning, Your Honor, For 16 Natera this is Karen Jacobs and Derek Fahnestock from Morris 17 Nichols. 18 We have on the line with us and will be arguing 19 today are Eric Stone and Eliza Strong from Groombridge Wu. 20 THE COURT: Okay. Good morning 21 All right. We have three issues. So let's start with the first issue dealing with the request of 22 23 plaintiff to compel the expert reports, deposition testimony

and corresponding exhibits of Natera's damages expert Ryan

Sullivan from the ArcherDX litigation.

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information, so to the extent the requested information has
 Natera's information, Natera's counsel can see that; it's
 odd to contend that they can't. But the strange concern
 that they seem to have is that they might be prohibited from
 seeing Invitae's information pursuant to that protective
 order. Well, it's a strange concern. We're asking them to
 produce the information.

If we thought there was a concern with them seeing the information, we would have said so. Of course Natera's outside counsel can see the information, we want them to produce it to us. So if there's any concern there, let's put that to doubt now; we're granting them permission to see the material so they can produce it to us.

They also complain that the protective order prohibits use in another case. Well, that's why we're asking them to produce it. It can't be that you can shield something from forever being used in another case by producing it in a second case, so that's why we're trying to get around this issue. We're asking them to produce it so we can use it in this case.

Just picking through their arguments, they cite the *AgroFresch* case, that's a case about production of settlement agreements where there appears to be a heightened standard. That's not what this is. Okay. This is not a settlement agreement situation.

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Filed 08/27/25 Case 1:21-cv-01635-GBW Document 302-1 Page 738 of 739 PageID

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admission unless Natera gave that -- called him to give that testimony at trial. And to the extent Natera did so, they have the trial testimony.

And after they see the expert report from us today, there is something that they think is inconsistent with his trial court testimony that is in the expert report, they can -- you know, they can ask us. But the notion that they should -- we should have to produce the expert report and deposition testimony of an expert in another case whom we are not calling in this case is exactly what Judge Bryson held in Pernix is irrelevant. And it can't lead to the discovery of admissible evidence at this point, fact discovery is over.

Let me make one more point because this is a new argument -- forgive me, that I don't think Mr. Walter made in the argument and I don't mean that pergoratively, I just want to make sure I respond to it. The notion that their expert can respond to hearsay because it is hearsay but experts can rely on hearsay, the rule is that experts can rely on hearsay of the type that is usually relied upon by experts in the field. Damages experts can rely on economic analyses, they can rely on the literature. You certainly cannot argue that an expert can rely on another parties' expert report because it is hearsay. The rule is not that experts can use all hearsay of any kind. The rule is that

3 that one expert can't rely upon something that another party 4 is saying is an authority in the field, that's erroneous. 5 Of course one expert can rely upon the statements of someone 6 else who the other party has said is an authority in the

statements or analysis, they are relying effectively upon

what other people in the field have said. And the notion

7 field; that's precisely the kind of stuff that experts rely 8 upon when they provide their testimony.

MR. STONE: Your Honor, I know that the Courts don't ordinarily entertain sur-rebuttal, but I must be doing a very bad job today because neither of those is the argument that I made. So just in the interest of full disclosure, the reason that I pointed out it's a different expert is that if it were the same expert, it would be a prior statement of the expert; we would be having a different conservation.

My point is simply it doesn't matter -- the reason that it matters that it's not Dr. Sullivan is that he's not testifying in the case.

And on the hearsay point -- on that I'll stop. We simply just --

THE COURT: Yeah. On this issue I do think it's fair game for Invitae to have access to that information for discovery purposes; whether or not it's admissible is another question. So I'm going to order the production with

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experts can use hearsay of the type ordinarily relied upon 2 by experts in the field. That rule has absolutely no 3 applicability here.

4 THE COURT: All right.

MR. WALTER: Your Honor, this is Derek Walter.

Should i respond briefly to some the points he

7 made?

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THE COURT: Yes, you can respond.

MR. WALTER: All right. So as to the first point that the expert that they plan to rely upon in this case is different from the expert that they relied upon in the first case, that's irrelevant.

What matters is Natera would have adopted the statements of their expert and they would have done so in either this trial or the previous trials; it doesn't have to be the same expert. Pernix doesn't say that, neither does Abstracts. In fact, I think in that Abstracts case we cited it was a different expert and that discovery was allowed. So the notion that it has to be the same expert, that's just wrona.

And then finally on the last point, the hearsay point, you know that's incorrect, too. It's incorrect that an expert in one field can't rely upon the testimony or the statements or the opinions of someone else in another field. That's what people do when they rely upon publications or

1 respect to the first request.

Let's move on to the second request.

3 MR. WALTER: Thank you, Your Honor.

4 The second request, I believe you -- the Natera

I'll just stick to the arguments here. The

5 sales data, that's the one I'm going to take next.

7 first thing they do is they complain that there's no 8 document request that relevant to this. That was a 9 surprising argument for us to see in this brief because it 10 was not once mentioned during meet and confer. If they

11 really thought that the lack of a document request was a

12 barrier here, they should have said so and we could have 13 remedied. So I think they've waived that argument. But

14 what's also really telling here is they don't submit the

15 document request we have in this case. And if you look at

16 the document request, which are not before the Court, I can

17 only tell you what's there, I think we probably do have

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document requests, Request 20 asks for documents relating to

19 identifying somatic sensations. Request 31 asks for things

20 related to the accused product. And to the extent that's

21 sold as a unit, that would be an accused products. Request

22 42 asks for the same sort of things. So the lack of

23 document request was kind of a strange and surprising

24 argument.

25 Also, they make an argument based on the merits.

	Case 1:21-cv-01635-GBW Document 302-1 Filed 08/27/25 Page 739 of 739 PageID
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1	at 10:38 a.m.)
2	I hereby certify the foregoing is a true
3	and accurate transcript from my stenographic notes in the
4	proceeding.
5	/s/ Michele L. Rolfe, RPR, CRR
	U.S. District Court
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